

# Pharma & Healthcare Update

December 29, 2021

## REGULATORY YEARLY WRAP 2021: HEALTHCARE IN INDIA

### INTRODUCTION

The past year has seen some significant developments in the healthcare sector in India. The passage of a new law to provide standards for education and services performed by allied and healthcare professions brings in a much-needed enactment in the healthcare sector in the country. Professionals such as technicians, physiotherapists, nutrition experts, ophthalmic sciences professionals, physician assistants and numerous others are now brought within the ambit of a separate legislation which regulates their profession. The National Commission for Homeopathy Act, 2020 and the National Commission for Indian System of Medicines Act, 2020 were also amended to give effect to the National Commissions for implementing the Acts.

We have discussed the major developments of 2021 in the healthcare sector below. For the developments in the pharma, medical devices and digital health sector, please refer to our pharma, medical device and digital health updates respectively.

### NATIONAL COMMISSION FOR ALLIED AND HEALTHCARE PROFESSIONS ACT PASSED BY THE PARLIAMENT

The National Commission for Allied and Healthcare Professions Act, 2021 ("**NCAHP Act**") was passed by the Lok Sabha and Rajya Sabha in early 2021 and came into force on May 25, 2021.

The NCAHP Act is intended to provide standards for education and services performed by allied and healthcare professions such as ophthalmic science professionals, cardiovascular technology professionals and behavioural health sciences professional. This includes compiling a list of recognised qualifications in respect of the allied and healthcare professions listed in the schedule to the NCAHP Act as well as the creation of a Central Register of Allied and Healthcare Professions where persons who have obtained recognised qualifications may enrol themselves prior to commencing practice.

The NCAHP Act also provides for the creation of a National Commission for Allied and Healthcare Professions ("**NCAHP**") which will be responsible for determining the scope of practice of each profession, basic standards of education, recognising qualifications, and arranging for exit licensing exams. As the NCAHP is yet to be established, no standards for education and practice have been prescribed for any of the recognised professions under the NCAHP Act.

While the National Medical Commission, is the regulatory body which regulates the medical education and medical professionals in India there is a lack of a body to regulate allied and healthcare professionals. In light of which the NCAHP Act requires the establishment of a professional council for each of the recognised professions which includes ophthalmic sciences professionals (such as optometrists) and others in addition to the NCAHP. The NCAHP Act provides for the constitution of the NCAHP wherein it provides that the President of the professional council and one other member will act as a part time member of the NCAHP. The NCAHP will be assisted by the members of the professional councils for understanding and implementing sound legal education standards and scope of professions of each practise regulated under the NCAHP Act.

### NATIONAL COMMISSION FOR HOMEOPATHY (AMENDMENT) ACT, 2020 NOTIFIED

National Commission for Homeopathy (Amendment) Act, 2021 ("**Homeopathy Amendment Act**") was notified in the gazette on August 18, 2021.<sup>1</sup> It amends the National Commission for Homeopathy Act, 2020 ("**Homeopathy Act**"). The Homeopathy Act replaced the Homeopathy Central Council Act, 1973 ("**HCC Act 1973**").

The Homeopathy Amendment Act specifies that all powers exercised, and functions performed by the Board of Governors (as under the HCC Act 1973) will be deemed to have been done under the Homeopathy Act and will continue to remain in force.

The HCC Act 1973 set up the Central Council of Homeopathy for regulating homeopathic education and practice. and to enable the regularization and maintenance of a central register of issues and entities related to the field of **homeopathy**. Although, the Homeopathy Act replaced the Council with a National Commission for regulating homeopathic education and practice ("**National Commission**") in 2021. Before the Homeopathy Act was passed, the Central Council was to be reconstituted within a year in line with the 2018 amendment to the HCC Act 1973. The HCC Act 1973 was also amended to provide that till the Council was reconstituted, its powers would be exercised by a Board of Governors, constituted by the central government. The National Commission was constituted on July 5, 2021 to supersede the Central Council and on the same date the HCC Act 1973 was repealed.

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October 31, 2024

### Analysing SEBI's Consultation Paper on Simplification of registration for FPIs

National Commission for Indian System of Medicine (Amendment) Act, 2021 ("**ISM Amendment Act**") was notified in the gazette on August 18, 2021.<sup>2</sup>

The ISM Amendment Act specifies that all powers and functions of the Board of Governors (as under the MCC Act) will be deemed to have been done under the ISM Act and will continue to remain in force.

The ISM Amendment Act amends the National Commission for Indian System of Medicine Act, 2020 ("**ISM Act**") which replaced the Indian Medicine Central Council Act, 1970 ("**MCC Act**"). The MCC Act set up the Central Council of Indian Medicine to regulate the education and practice of the Indian Medicine system (including Ayurveda, Yoga, Naturopathy). The ISM Act subsequently replaced the Council with a National Commission for regulating education and practice of the Indian medicine system although the constitution of the National Commission was delayed, and the ISM Act failed to repeal the previous act. In light of which the MCC Act was amended in 2020 to reconstitute the Central Council within a year. The MCC Act provided that until the council was reconstituted the Board of Governors constituted by the Central Government would exercise the powers vested in the Central council. The National Commission was constituted on June 11, 2021 to supersede the Central Council and on the same date the MCC Act was repealed.

## CONCLUSION

While the number of developments in the healthcare space have been sparse, the impact of each of them is significant. Both the NCAHP Act and the amendments to Homeopathy Act and Medicine Systems Act were long-awaited reforms that have been in the wings since 2019. The NCAHP Act has brought within its ambit all allied healthcare professionals by proposing to establish the NCAHP which will regulate the education and practise of various allied healthcare professions in India. Subsequently, developments have also been noticed in the Homeopathy and Indian medicine systems in our country with due constitution of the National Commissions regulating each of the said practices and the medical education in this regard. In 2022, we are excited to see the impact of these laws at the implementation level with greater responsibility and regulation of allied healthcare professionals which is aimed at introducing uniformity in approach, learning and handling as well as in ensuring patient safety in the country.

– **Varsha Rajesh, Tanya Kukade, Darren Punnen & Dr. Milind Antani**

You can direct your queries or comments to the authors

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<sup>1</sup> Available at: [https://prsindia.org/files/bills\\_acts/bills\\_parliament/2021/The%20National%20Commission%20for%20Homoeopathy%20\(Amendment\)%20Act,%202021.pdf](https://prsindia.org/files/bills_acts/bills_parliament/2021/The%20National%20Commission%20for%20Homoeopathy%20(Amendment)%20Act,%202021.pdf) (Last accessed on September 23, 2021).

<sup>2</sup> Available at: [https://prsindia.org/files/bills\\_acts/bills\\_parliament/2021/The%20National%20Commission%20for%20Indian%20System%20of%20Medicine%20\(Amendment\)%20Act,%202021.pdf](https://prsindia.org/files/bills_acts/bills_parliament/2021/The%20National%20Commission%20for%20Indian%20System%20of%20Medicine%20(Amendment)%20Act,%202021.pdf) (Last accessed on September 23, 2021)

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September 22, 2024