

## **Insights and Commentary from Dentons**

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**April 2023**



## Weekly Insights & Updates

**9 August 2022**

As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathic drugs, is vested with the State drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to I) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathic medicines. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with the Good Manufacturing Practices (GMP) as per Schedule T & Schedule M-I of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

### Budget Allocation and Utilization of Funds under National Ayush Mission

Under Centrally Sponsored Scheme of the National Ayush Mission, the total budget of Rs. 3119.46 crores has been allocated/ released as a central share to States/UTs since the inception of the scheme and they have reported an expenditure of Rs. 2290.20 crores. Government of India has adopted a strategy of Co-location of Ayush facilities at Primary Health Centres (PHCs), Community Health Centres (CHCs) and District Hospitals (DHs), thus enabling the choice to the patients for different systems of medicines under a single window. The engagement of Ayush doctors/ paramedics and their training is supported by the Ministry of Health & Family Welfare under National Health Mission (NHM), while the support for Ayush infrastructure, equipment/ furniture and medicines are provided by the Ministry of Ayush under National Ayush Mission (NAM) as shared responsibilities.

**Link to press release**

## Development of Ayush Entrepreneurship

For the purpose of development of the Ayush entrepreneurship Ministry of Ayush had developed a Central Sector Scheme namely Champion Services Sector Scheme for Medical Value Travel for

implementation on Pan India basis. Under this scheme, financial assistance in the form of Interest Subsidy is provided to private investors for the establishment of Super Specialty Hospitals/ Day Care Centres of the systems recognized under The National Commission for Indian System of Medicine (NCISM) Act, 2020 or The National Commission for Homeopathy (NCH) Act, 2020.

[Link to press release](#)

### **Ayushman Bharat Digital Mission (ABDM) making steady progress in digitizing and linking health records of citizens with their ABHA numbers**

The National Health Authority (NHA) under its flagship scheme Ayushman Bharat Digital Mission (ABDM) is building a comprehensive digital health ecosystem for the country. Since nationwide launch in September 2021, ABDM has achieved significant growth with over 23 crore ABHA numbers (earlier known as Health ID), 1.14 Lakh health facilities registered in the Health Facility Registry (HFR), 33 thousand healthcare professionals under the Healthcare Professionals Registry (HPR), 6.6 lakh ABHA app downloads and 3.4 Lakh health records linked to ABHA of individuals.

[Link to press release](#)

### **Measures to tackle Black Marketing of Blood**

It is primarily the responsibility of the State/UT Government to take concrete steps to prevent illegal activities taking place in blood banks and during blood transfusion. Government has made registration of blood banks mandatory as per the provisions of Drugs and Cosmetic Act and Rules thereunder. Further, Government has notified Drugs and Cosmetics (Second Amendment) Rules, 2020 which pertain to functioning of Blood Banks/centres, Blood processing and related matters. The implementation & monitoring of aforesaid Act and Rules is within the ambit of the States/UTs. A letter has been issued to States/UTs to take concrete steps for prevention of such illegal activities.

[Link to press release](#)

### **Steps taken under Anaemia Mukh Bharat (AMB) strategy**

The Government of India implements Anaemia Mukh Bharat (AMB) strategy under POSHAN Abhiyaan with the target for reducing anaemia in the six population groups - Children (6-59 months), Children (5-9 years), Adolescents girls and boys (10-19 years), Pregnant women, Lactating women and Women of Reproductive Age (WRA) group (15-49 years) in life cycle approach. Some of the major interventions by Ministry of Health and Family Welfare (MoHFW) to address anaemia under AMB include:

- Prophylactic Iron and Folic Acid Supplementation.
- Deworming.
- Intensified year-round Behaviour Change Communication (BCC) Campaign and delayed cord clamping.
- Testing of anaemia using digital methods and point of care treatment.
- Addressing non-nutritional causes of anaemia in endemic pockets with special focus on malaria, hemoglobinopathies and fluorosis.
- Convergence and coordination with line department and other ministries.
- Engaging National Centre of Excellence and Advanced research on Anaemia Control for capacity building of health care providers.
- Monitoring progress in States/UTs using Anaemia Mukh Bharat Dashboard.

[Link to press release](#)

### **Proposal to send specialist doctors to rural areas**

As per the District Residency Program notified by the Board of Governors, all the post graduate students pursuing MD/MS in broad specialties in all Medical Colleges/Institutes under the Indian Medical Council Act, 1956 shall undergo a compulsory residential rotation of three months in District Hospitals/ District Health System as a part of the course curriculum.

[Link to press release](#)

## **Role of National Family Health Survey (NFHS)**

The National Health Authority (NHA) announced expansion of the digital health ecosystem being built under its flagship scheme Ayushman Bharat Digital Mission (ABDM) with successful integrations of 52 digital health applications. In the last two months, additional 12 health service applications completed their integration across various milestones in the ABDM sandbox environment. After a successful demonstration, these applications were added to the ABDM Partners ecosystem. The tally now includes 20 government applications and 32 private sector applications.

[Link to press release](#)

## **Anti-fraud system for India's National Health Insurance Scheme (AB-PMJAY)**

Ayushman Bharat –Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) is governed on a zero-tolerance approach to any kind of fraud viz. suspect/non-genuine medical treatment claims, impersonation and up-coding of treatment packages/procedures etc. The Government of India adopts a pro-active approach towards fraud and abuse. It goes on to underscore that several countervailing strategies have been employed under PM-JAY to address various types of fraud and it acknowledges the success of the AI-based technologies deployed under the scheme.

[Link to press release](#)

## **National Health Authority (NHA) joins hands with Quality Council of India (QCI) to accredit ABDM compliant healthcare solutions like HMIS/LMIS**

The National Health Authority (NHA) has onboarded the Quality Council of India (QCI) for six months to accredit and rate HMIS (Health Management Information System)/ LMIS (Laboratory Information Management System) solutions that have integrated with Ayushman Bharat Digital Mission (ABDM). The National Accreditation Board for Hospitals and Healthcare Providers (NABH), the constituent board of QCI is responsible for national accreditation in the domain of healthcare. NABH will undertake the responsibility of accrediting and rating the ABDM compliant solutions on various parameters, including ease of usage, user interface, pricing, number of modules/features and value for money/pricing so that prospective purchasers may get credible information.

[Link to press release](#)

## **New Ayush wings in Defence and Railway Hospitals**

Ministry of Ayush signed a MoU with Ministry of Railway for Introduction of Ayush Systems in five Railways Hospitals resulting into establishment of Ayush units at 5 Railway zonal hospitals at Delhi, Mumbai, Chennai, Kolkata and Guwahati. Ministry of Ayush has collaborated with Ministry of Defence resulting in the establishment of Ayurveda OPDs at 12 AFMS (Armed Force Medical Services) Hospitals and 37 Cantonment Board Hospitals. These facilities are successfully operational with effect from 1st week of June 2022.

[Link to press release](#)

## **Pharmacopoeia Commission for Indian Medicine**

The Government of India has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), as a subordinate office under Ministry of Ayush by merging Pharmacopoeia Commission of Indian Medicine & Homoeopathy (PCIM&H) and the two central laboratories namely Pharmacopoeia Laboratory for Indian Medicine (PLIM), Ghaziabad and Homoeopathic Pharmacopoeia Laboratory (HPL) vide gazette dated July 6, 2020).

[Link to press release](#)

## **Preparedness and response activities against biological emergencies**

Ministry of Health and Family Welfare provides requisite guidance and logistic support to the States/UTs. The Integrated Disease Surveillance Programme through its State and District units



conducts disease surveillance in the country through a decentralized State based surveillance system for epidemic prone diseases to detect the early warning signals, so that effective public health actions can be initiated in response to health challenges in the country.

[Link to press release](#)

**Steps to strengthen the Healthcare System in India**

The healthcare system of the country involves a three-tier system with Sub Health Centre (Urban and Rural), Primary Health Centre (Urban and Rural) and Community Health Centre (Urban and Rural) as the three pillars of Primary Health Care System in India. Rural Health Statistics (RHS) is an annual publication, based on Health care administrative data reported by States/UTs.

[Link to press release](#)

**Update on Free Diagnostics Service Initiative’ (FDSI)**

The Ministry of Health and Family Welfare, Government of India supports ‘Free Diagnostics Service Initiative’ (FDSI) programme under National Health Mission. The programme was launched in July 2015, with the aim to provide accessible and affordable pathological and radiological diagnostics services closer to the community which in turn reduces the Out-of-Pocket Expenditure (OOPE). A minimum set of essential diagnostic tests has been recommended as per the Essential Diagnostic List at each level of public health facility.

[Link to press release](#)

Please feel free to reach out to the following members of our Healthcare team for any questions:

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