

Acclimating to the new world order in Bahrain: the realignment of public health priorities post- COVID-19

Foutoun Hajjar - Partner, Head of Office - Bahrain - Corporate / Mergers & Acquisitions / Commercial / Capital Markets

f.hajjar@tamimi.com - Manama

Hussain Osman

h.osman@tamimi.com - Manama

When COVID-19 brought the world to a standstill, the Kingdom of Bahrain sought to adjust its current regulatory standing by adopting a set of measures aimed to expedite drug delivery, ensure pharmaceutical product safety during freight, and enable the adoption of tele-health solutions in light of social distancing. Furthermore, in September 2020, the Bahrain Medical Society ('BMS') took a quantum leap by adopting the World Health Organization's Occupational Health Charter in order to safeguard the physical and mental well-being of the Kingdom's key asset - the human resource.

This article considers the National Health Regulatory Authority of Bahrain ('NHRA') 'mayday' measures stemming from the broader provisions contained within Law 34 of 2018 promulgating the Public Health Law (the 'PHL'). Furthermore, an introduction to Bahrain's efforts towards institutionalising the provision of mental healthcare through regulating the functions and requirements of incorporating rehabilitation facilities will be briefly touched upon.

A blessing in disguise: applying the PHL to combat COVID-19

The flexibility of the PHL was most visible recently during the wake of the pandemic. Article 44 enables the Ministry of Health ('MOH') to exercise broad executive powers in combating the spread of all communicable diseases, by granting it a prerogative to establish adequate measures pertinent to each outbreak. This provision allows the MOH to tailor its policies on a case-by-case basis, depending on the nature of the pandemic.

Furthermore, the PHL vests the MOH with powers to install specific standards aimed both at preventing the transmission of infection across medical institutions, and the contamination of the environment. This protects the public from diseases that may originate from healthcare institutions, and offers security to patients who are hospitalised because of an unrelated condition, thereby safeguarding all members of the public irrespective of levels of vulnerability. Moreover, the elastic nature of the legislation governing public health allowed for the creation of mobile medical units across Bahrain to examine people in their homes.

The PHL dedicated key reporting mechanisms to illustrate the hierarchy of responsibility in relation to reporting an infected individual, ranging from the physician to the relatives of the patient. Further, Article 39 provides a list of all parties responsible for reporting a suspected case of a communicable disease to help prevent its spread. Moreover, any person who is infected or is suspected of being infected with a communicable disease must be isolated at a hospital or at a location as determined by the MOH.

Procedures for importing non- registered medicines and pharmaceutical products

In line with Resolution 32 of 2020 on Pharmaceutical Product Registration System and Prices, the NHRA swiftly issued Circular 41 of 2020 setting out the conditions and requirements of importing pharmaceutical products that are currently not registered. As the world witnesses a current hike in R&D activity attributed to the global call to 'find the vaccine', many inventive biologic and conventional drugs are expected to enter the local Bahraini market. Moreover, this modern pathway to import emergency drugs was highly commended by the international community as it offers a legitimate track to obtain vital interventions, thereby catering to distressed patients seeking a lifeline while combatting the logistical interruptions due to the current pandemic.

The following conditions are to be met in order to import non-registered medicines and pharmaceutical products by Public and Private Medical Hospitals ('PPMH'):

1. the PPMH must provide sufficient evidence that no registered alternative medicine or pharmaceutical product is available in Bahrain;
2. the medicines or pharmaceutical products are registered with the Gulf Health Council or with one of the countries of the Gulf Cooperation Council for the Arab Gulf States;
3. the medicines or pharmaceutical products are identifiable or registered with any of the following reference health product regulatory authorities:
 - I. (FDA) – US Food and Drug Administration;
 - II. (HEALTH CANADA)
 - III. (EMA) – European Medicines Authority or a Western European country.
 - IV. (SWISSMEDIC)
 - V. (TGA) – Australian Medicines Administration.
 - VI. (PMDA) – Japanese Ministry of Health.
 - VII. (MHRA) – British Medicines and Health Products Authority.
4. the medicine or pharmaceutical products are marketed in the country of origin;
5. the manufacturing company must be registered with the NHRA manufacturers register or the Gulf Health Council;
6. the trade name, scientific name, strength, storage conditions, batch number, pharmaceutical form, production and expiry date, and the name and address of the manufacturer must be made available; and
7. imported batches must be transported and preserved in containers according to the conditions of transport and storage suggested by the manufacturer.

Upon the satisfaction of the abovementioned conditions, the NHRA requires the PPMH to append copies of the pharmaceutical product certificate ('CPP') and the good manufacturing practice ('GMP') certificate of the manufacturer prior to issuing an import permit. Furthermore, pharmaceutical agents in Bahrain are expected to comply with similar conditions for the importation of non-registered pharmaceutical products.

Adopting NHRA-MVC traceability hub for pharmaceutical product traceability

In line with the NHRA's Medicines Barcoding and Serialization Guidelines, pharmaceutical manufacturers are now required to sign up to the NHRA-MVC Traceability Hub before January 2021 and obtain the adequate GS1 barcoding certificate no later than 1 October 2021 in order to comply with current importing standards. This landmark announcement places Bahrain on a par with the international community's pharmaceutical surveillance effort by emulating the policies and functions of the European Medicines

Verification System. As such, all drug manufacturers and distributors must commit to attaching the Global Trade Item Number ('GTIN') on their packages in an attempt combat the trade of counterfeit pharmaceutical products in Bahrain.

Dispensing through the cloud

In 2020, the NHRA issued the first telemedicine licence in Bahrain to Doctori, a state-of-the-art telemedicine application aimed to serve a community at a time of distress. At the same time, it was announced that the NHRA would issue a guiding document aimed towards regulating drug- dispensing activity through mobile application.

Version (1) of the Telemedicine Guidelines was issued in July 2020, thereby allowing telemedicine consultations to take place thorough licensed medical practitioners in Bahrain. Substantial discretion has been given to Licensed Medical Practitioners ('LMP') in that if a medical condition requires a particular protocol to diagnose and prescribe, as in cases of in-person consultations, the same principle will be applicable to telemedicine consultations.

LMPs are thereby permitted to prescribe medicines via telemedicine if they are satisfied that they have adequate and relevant information about the patient's medical condition, and that prescribed medicines are in the best interests of the patient. Henceforth, prescribing medicines in the absence of a suitable diagnosis report will amount to professional misconduct.

The NHRA categorised a list of medicines that may be prescribed following a virtual consultation. These have been divided into three categories: List P, List POM, and the Prohibited List.

List P comprises medicines that are safe for prescription through any mode of tele- consultation. In essence, these include:

1. medicines that are used for common conditions and are often available as 'pharmacy only', e.: paracetamol, ORS solutions, and cough lozenges; and
2. medicines that may be deemed necessary during public health emergencies.

List POM (prescription only medicines): These medications may be prescribed during the initial video consultation and by follow-up prescriptions such as: clotrimazole, mupirocin, calamine lotion, benzyl benzoate lotion, local ophthalmological prescriptions and hypertension prescriptions.

Prohibited List: Namely, narcotic and psychotropic items.

Furthermore, any prescription issued via electronic mediums must contain all the relevant information appearing on the MOH's generic prescription sheet as well as containing the LMP stamp bearing his/her professional licence number.

Institutionalising the delivery of mental healthcare in Bahrain

On the margins of the virtual signing ceremony inducting Bahrain as an observer of the World Health Organization's Occupational Health Charter, the general secretary of the BMS informed media outlets that "in addition to the physical risks, the pandemic has exposed health workers to extraordinary levels of psychological pressure as a result of working extended hours in demanding conditions, and living in

constant fear of exposure to the virus while separated from family.”

With growing fears and apprehension towards the future of our mental wellbeing, NHRA introduced a governing framework aimed at institutionalising the treatment and delivery of mental care in Bahrain. This step entails embracing the importance of collective action aimed towards enhancing the current policy frameworks governing a key area of non-communicable diseases shrouded in taboo and gone astray. As such, Resolution 33 of 2020 extended a hand of support to the most vulnerable category of mental health patient – victims of addiction.

Applicants willing to obtain a commercial licence to run a rehabilitation facility are required to approbate their engineering sketches by the Healthcare Facilities Department – NHRA in addition to ensuring that day-to-day functions are supervised by a licensed medical consultant. Furthermore, rehabilitation facilities are required to follow modern diagnostic methods implemented internationally through a qualified medical cadre. As such, Article 10 sets out the minimum medical qualifications to be held by each member; namely:

1. **Physician:** licensed by the NHRA, holding a fellowship in psychiatry, specialised training in addiction treatment for a period of at least two years;
2. **Psychology Specialist:** licensed by the NHRA, holding a bachelor’s degree in clinical psychology in addition to six months training in addiction treatment or (alternatively) a master’s degree in psychology;
3. **Clinical Nutrition Specialist:** licensed by the NHRA, holding a bachelor’s degree in clinical nutrition;
4. **Occupational Therapy Specialist:** licensed by the NHRA, holding an accredited bachelor’s degree in occupational therapy specialising in either mental health or psychology. A minimum of three years of practical experience is required;
5. **Physiotherapist:** licensed by the NHRA, holding an accredited bachelor’s degree in physiotherapy; and
6. **Qualified Psychiatric Nurse:** licensed by the NHRA, holding a bachelor’s degree in nursing and a higher diploma in nursing mental health, in addition to practical training for a period of no less than one year in the field of psychiatry.

Conclusion

The application of the PHL throughout COVID-19 tested the legislation, and demonstrated its flexibility and durability. The practical assessment of the PHL validated its success by corroborating the advantages of implementing harsh sanctions, as well as having flexible provisions to personalise each exposition reliant on it. The Kingdom of Bahrain is committed to the health and wellbeing of its citizens, and the government has adopted a modern trajectory by incorporating modern technology into everyday life with the chief aims of enhancing healthcare delivery, and the protection of potential new entrants into the local market.

For further information, please contact healthcare@tamimi.com.

