

A Quick Guide to the Iraqi Healthcare Industry

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This article will cover both well-established law for trade in medicines and new developments opening Iraq's healthcare sector to private investment. We will start with the trade aspect and cover the import process. Then we will move to the legal framework specific to investing in healthcare in Iraq.

Trade in medical products

Importation of medical products, which include medicines, cosmetics, and medical appliances, can follow different business models depending on who the buyer is. There are two broad possibilities in Iraq: the buyer can be the State company for marketing drugs and medical appliances ('KIMADIA') or it can be a buyer from the Iraqi private market. On the public procurement side, KIMADIA is the only governmental body authorised to import medical products on behalf of the Iraqi government, and it does so using the usual regulations for public tendering applicable in Iraq. When KIMADIA solicits bids for public tenders, it follows regulations no 1 and 2 of 2014 on implementing government contracts. This entails certain contracting requirements that must be followed by the bidder, such as submitting preliminary guarantees with bids and posting performance bonds from an acceptable local bank, prior to KIMADIA awarding a bid.

According to Iraq's Pharmaceutical Law (Federal Law No. 40 of 1970) and accompanying instructions (Instructions No. 4 of 1998) regulating scientific offices in the business of marketing pharmaceutical products, importing medical products to Iraq must be done exclusively through Iraqi registered third parties 'scientific offices'. The only exception is if KIMADIA deems it necessary to import products directly. While KIMADIA has the authority to deal directly with non-Iraqi manufacturers or marketers, it still prefers to deal through Iraqi registered scientific offices whenever possible. Where dealing with the Iraqi private sector, the only way to trade in medical products is through a scientific office.

There are two relevant regulators in the Iraqi healthcare sector, the Ministry of Health and Environment ('Ministry of Health') and the Syndicate of Iraqi Pharmacists. Generally speaking the following should be kept in mind when importing medical products to Iraq,

- There are income tax obligations when doing business through third party agents, i.e. scientific offices, as this is considered doing business in Iraq by the relevant tax authorities;
- To import or market medical products, both the manufacturer and the medical product need to be registered with the Ministry of Health, who keeps a list of registered products and manufacturers;
- To register a manufacturer, the Ministry of health requires a number of documents including, but not limited to, the manufacturer's / vendor's articles of incorporation, letters of authorisation, manufacturing licence, Israel boycott letter, and Good Manufacturing Practice ('GMP') and Certificate of Pharmaceutical Product ('CCP') certificates;
- The required documents are different from originating country to country, depending on which authorities are responsible for granting approvals for the manufacturing and selling medical products in the country of origin;

- All submitted documents need to be properly legalised and stamped, as per Iraqi law;
- For products originating from certain countries, and in certain cases, the Ministry of Health will require the applying party to pay for Ministry inspectors to visit and inspect production facilities;
- Changes affecting information provided to the Ministry of Health need to be updated for the registration to remain active;
- Registrations need to be renewed after five years, in most cases;
- Import licences are issued to scientific offices to import a specific product prior to import, and, as an exception, to parties dealing directly with KIMADIA;
- There are certain circumstances where KIMADIA will provide assistance to importers to expedite the registration process at the Ministry of Health for performance of awarded bids;
- Scientific offices can carry out registration at the Ministry of Health, and bid on behalf of the parties they represent using properly notarised authorisation letters;
- No more than one scientific office can be used to market the same medical product, but multiple offices can be engaged to market different products;
- Scientific offices can be agents acting on behalf of their principles or distributors acting on their own;
- Scientific offices must be operated by Iraqis and, if they are an incorporated entity, must be fully owned by Iraqis.

Investing in Iraq's healthcare sector

In 2015, the Iraqi parliament passed the Law on Establishing Private Healthcare Institutions (Federal Law No. 25 of 2015) (the 'Private Healthcare Institutions Law'), which came into force on 29 June 2015. The new law repealed the old private hospitals law (Federal Law No. 25 of 1985) and some articles in the public health law (Federal Law No. 89 of 1981). The Private Healthcare Institutions Law included major developments and improved the legal framework for private investment in healthcare. The Ministry of Health will issue regulations detailing how it intends to implement the new law. In the meantime, we can point out the following incentives and changes introduced by the new law:

- Repealing parts of the public health law requiring licence holders to be Iraqis and allowing non-Iraqis to apply for licences to operate healthcare institutions;
- Allowing incorporation of entities with the purpose of operating healthcare institutions, with the approval of the Ministry of Health;
- Exempting health care institutions from income tax for the first three years from actual operation, as supported by the Ministry of Health;
- Allowing further employment of foreign staff up to certain percentages, depending on the type of employed staff;
- Allowing land allocation for free, with approval from the Ministry of Health;
- Allowing loans of up to 30 per cent of the cost of establishing hospitals, with the approval of the Ministry of Health.

The Private Healthcare Institutions Law is not the only piece of applicable legislation with incentives. Depending on how the investment is structured, it can be a second, more specific, layer which operates on top of the Investment Law (Federal Law No. 13 of 2006), with its two amendments. Unlike the Investment Law, which requires holding a licence from the National Investment Commission ('NIC') to enjoy its benefits, the Private Healthcare Institutions Law does not require prior approval from the NIC. Since Iraqi corporate law allows foreign parties to own 100 per cent of Iraqi corporations, investors can choose to operate without an investment licence. Regardless of the path investors choose to follow, the Ministry of Health remains the relevant regulator for healthcare businesses.

Conclusion

Dealing with the Iraqi healthcare industry must be done through licensed Iraqi third parties; the only exception is public tenders from KIMADIA. Prior registration of products as well as manufacturers and vendors is required to grant import licences. As far as private investment is concerned, the new Private Healthcare Institutions Law marks a positive development for private investment in the healthcare industry, opening it to foreign capital and creating lucrative opportunities for investment in Iraq.

Al Tamimi & Company's Iraq team regularly advises on healthcare law. For further information, please contact Ali Al Dabbagh (A.AIDabbagh@tamimi.com) or Jawad Khalaf (J.Khalaf@tamimi.com).