New Legislation in Israel for Medical Device Registration and the Role of the Israeli Registration Holder (IRH)

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Introduction: The New Legislation

In May 2012 Israel’s parliament passed new legislation pertaining to the registration of medical devices in Israel (Medical Devices – 2012, #5772-2012). The law was approved almost a decade after it was first proposed in 2004 and is being implemented gradually during 2013. Under this legislation, all medical devices manufactured or marketed in Israel must now be registered with AMAR, the Medical Device Division of the Israeli Ministry of Health, which is responsible for the registration and supervision of medical devices in Israel. With an impressive share of the global medical device market, Israel is becoming an international leader in developing innovative medical devices. This legislation will have an impact on companies seeking to manufacture and/or market their device in Israel.

Prior to the 2012 legislation, medical device registration was voluntary in Israel and only those medical devices supplied to government medical institutions were required to be registered with AMAR. Registration with AMAR is well respected, and thus in the past many manufacturers had registered their devices even though they were not required to do so. So the major change with this legislation is that device registration, and labelling as to the approved indication(s), is now mandatory for devices manufactured and marketed in Israel. The new law imposes a criminal prohibition on manufacturing, importing, marketing, or using medical equipment that has not been registered with AMAR, except in rare cases and with the approval of the Israeli Ministry of Health. Registration of medical devices in Israel is based on having prior approval in one of following countries: Australia, Canada, EU, Iceland, Norway, New Zealand, Switzerland, Japan, or the United States. This article covers the requirements for the position of “Israeli Registration Holder” (IRH), which is one of the most important requirements laid out in the new law.

Healthcare in Israel

The healthcare system in Israel, one of the largest in the Middle East, is both universal and compulsory, ensuring that all citizens of Israel are covered. It is administered by a few organizations with funding from the government. All Israeli citizens are entitled to the same uniform, government-determined benefit package (sal briyut), regardless of their employment or financial means. National “sickness funds” may not bar applicants on any grounds, including age or state of health. Equal status is accorded to all four sickness funds. Services are offered in the areas of family medicine, emergency treatment, elective surgery, transplants, and medications.

The leading indicator in the health rankings is life expectancy, in which Israel is well ahead of many Western nations. Israeli men have the second-highest life expectancy among developed countries: 79.7 years on average, with only Switzerland above it with 80.3 years. This is well above Britain at 78.6 years, Germany and France at 78, and the United States at 76.2. For women, the life expectancy figure is 84 years, in eighth place, but still very close to the top (Israel Central Bureau for Statistics, 2013).

Israel has become recognized worldwide for its numerous innovative and cutting-edge contributions in medical technology. These advances have been enabled, in part, by a close network of cooperative relationships between medical research institutions and industry.

The Israeli Medical Device Industry

Israel is one of the world’s leading centers for the development of innovative medical devices. The country has a very high proportion per population of new patents in this sector compared to other countries. There are nearly 800 Israeli companies in the medical device field, which comprises about half of Israel’s life sciences sector (Israel Ministry of Industry, Trade & Labor Investment, 2012).

Israel’s strength in this sector comes from multi-disciplinary capabilities, bringing together medicine, engineering, clinical expertise, and software development. Some of the world’s leading universities, with renowned R&D faculties, leading-edge medical centers, the world’s highest per-capita number of physicians, and a remarkable high-
tech sector combined with a spirit of entrepreneurship, have all contributed to a dynamic growth in medical device innovation in Israel. In recent years Israel’s medical device sector is attracting increasing amounts of foreign investment. This is achieved through VC funds, IPOs, and direct investments from major US and international companies such as Johnson & Johnson, Boston Scientific, Medtronic, and Guidant.

**The Israeli Registration Holder**

Israel’s new Medical Devices law will change the medical device industry in Israel and adds an administrative layer in that all device companies will need to liaise with, and oversee compliance with, AMAR. According to *Section 3(d)*, applications for registration can be done only by an Israeli citizen or by a corporation established in Israel. Companies intending to export their devices to Israel will thus need to appoint a third party in Israel with the appropriate knowledge and skills to function as the Israeli Registration Holder (IRH), who will oversee the medical device registration process and maintain any approvals granted by AMAR. In many respects, this IRH position mirrors the US FDA “agent” and EU “Authorized Representative” models. Using an independent IRH will provide more freedom when selecting distributors or when changing distributors, and will keep confidential company information independent of these changes and in the hands of a professional entity without commercial interest in the product.

The IRH is responsible for the following activities:

1. Reside and maintain a place of business in Israel and serve as the regulatory representative [*Section 3(b)*].
2. Prepare and submit the registration application to AMAR [*Section 3(b)*].
3. Review the first batch of devices to be marketed in Israel as requested by AMAR [*Section 7(a)1*].
4. Respond to questions from AMAR concerning the registered products [*Section 15(b)*].
5. Report adverse events to AMAR [*Section 15(b)*].
6. Renew the registration on time to keep the market approval active [*Section 8*].
7. Receive documents from AMAR on behalf of the legal manufacturer and liaise with the registrar [*Sections 9(b) and 12*].
8. Comply with postmarketing requirements (*ref. section 11*), including:
   - Evaluate information provided by users
   - Forward it to the legal manufacturer
   - Prepare periodical postmarketing reports (upon request)
   - Report adverse and unexpected events occurring in Israel or in other countries where the device is in use
   - Report restrictions from other regulatory bodies concerning the registered device

**Advantages of an Independent IRH**

Although a distributor of medical devices can act as the regulatory representative in Israel, there are several reasons for selecting an independent, professional IRH:

- Extensive experience with Regulatory Affairs and with Israeli regulations in particular
- IRHs that deal only with regulatory issues have no commercial interest in the product
- Potential problems associated with switching distributors can be encountered if a
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- A poorly performing distributor is also the IRH
- Competitive problems can occur if one distributor acts as the IRH and the legal manufacturer wishes to appoint a second distributor, or the distributor represents other legal manufacturers with competitive products
- Avoid having to entrust the distributor with the proprietary product design information
- Avoid distributor conflicts of interest in the event of a product recall or incident report to AMAR
- Avoid having to rely on the distributor for regulatory updates in Israel

Conclusion
This challenging new situation requires those who manufacture and market medical devices in Israel to be aware of the implications of the new medical devices law and to align accordingly. Importantly, the new regulations will have the biggest impact on small to medium-sized companies outside of Israel who may not have a registered office in Israel and are only carrying out sales through local distributors. The new requirement to have an IRH with a place of business in Israel will force firms to either open an office in Israel or to appoint another company in Israel as their representative. This approach is similar to those found in other markets such as China and Brazil. It is equally important to consider the legal and regulatory requirements of medical device reporting to the authorities, which makes the position of IRH an ongoing responsibility that must demonstrate independence from potential conflicts of interest should product issues arise. Any decision to appoint a distributor as your IRH should be carefully considered.

References/Resources


Israel Ministry of Economy. Invest in Israel. Available at: http://www.investinisrael.gov.il
