



# MEDICAL DEVICE TRANSLATION NEWS

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## Turkey: a promising market for medical technology

By Jeanette Marchant—London, UK

As negotiation of Turkey's entry into the European Union gets under way, the country is gearing up for EU membership. Although it will be at least a decade before the country is admitted to the current bloc of 25 member states, Turkey has embraced the European currency and the euro is accepted as legal currency in many major cities. The government has laid the foundations for harmonizing its legislation with that of the EU and in 2004 adopted the Active Implantable Medical Device Directive, the Medical Device Directive and the In vitro Diagnostics Directive.

Around 60% of Turkey's 67 million population lives in cities: Istanbul is by far the largest with a population of over 10 million, followed by the capital Ankara with 4 million and Izmir with over 3 million. Although the healthcare system aims to cover the total population, an estimated 20% of inhabitants are uninsured and a key element of Turkey's healthcare reform program is to put in place a unified public health insurance system.

**Imports of medical devices of US origin that are approved by the Food and Drug Administration but do not possess a CE mark are "nearly impossible", according to AdvaMed**

Currently, the social insurance system (SSK) acts as both healthcare provider and insurer for around 65% of the population, while separate funds provide healthcare insurance coverage for the self-employed and for retired public sector employees and their families. The Green Card Scheme funded by the government provides basic healthcare for low income individuals who do not have health insurance. Private insurance, which is estimated to cover just 2% of the population, tends to be provided by employers as part of benefit packages to employees.

### Private Health Facilities Growing

Healthcare services in the fragmented healthcare system are provided through the government, SSK, medical schools and private sector. In the last decade private health facilities have experienced a boom, doubling in numbers to 241. More than half of the private hospitals are in Istanbul, where private facilities provide the largest share of beds: of the 197 hospitals in Istanbul, 138 are private institutions. Istanbul's healthcare services, however, are not

representative of the national distribution of hospitals. While privatization of the hospital sector is envisaged under the reform program, the Ministry of Health currently owns around half the bed capacity in Turkey.

Concomitant with the development of private hospitals in the last decade, there has also been a growth in private polyclinics and diagnostics centers which provide a range of outpatient services under one roof. Further expansion of the private sector will be driven by growing demand for private healthcare by higher income groups as well as foreign patients from Europe and the Middle East. Anticipated increases in private medical insurance will also help stimulate use of private health services. Although GDP per capita remains low at a fraction of the poorest of the EU member states (US\$1,362 compared with US\$6,516 for Poland in 2004), the Turkish economy is growing more rapidly than any of the EU members with GDP increasing 9% in 2004. This is contributing to an expanding affluent segment of the population.

The Ministry of Health is the largest single purchaser of medical equipment, although demand for the latest technology is highest in the private sector. Purchasing procedures are also less complex in the private sector than the tender system which is the norm for public procurement.

The Turkish market for medical technology is growing at around 10–12%, according to the Association of Health Equipment Providers, driven by imports which reached US\$415 million in 2002. Key imports include imaging

Ownership	No. of Hospitals	Bed Capacity	% of Total Beds
Ministry of Health	654	88,827	49.9%
Ministry of National Defence	42	15,900	8.9%
SSK	120	28,979	16.3%
University	50	26,024	14.6%
Other Ministries	2	680	0.4%
Municipalities	10	1,389	0.8%
State economy enterprises	8	1,607	0.9%
Associations	20	1,587	0.9%
Foreign	4	338	0.2%
Minority	5	934	0.5%
Private	241	11,870	6.7%
<b>TOTAL</b>	<b>1,156</b>	<b>178,135</b>	<b>100%</b>

Source: Turkish Ministry of Health

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**According to the US advanced medical technology trade association, AdvaMed, manufacturers without a valid A.TR-1 form must submit a CE mark certificate, a Declaration of Conformity and labels and instruction manuals in Turkish in order to export medical devices to Turkey.**

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equipment, electromedical equipment, syringes, needles, catheters, surgical instruments, and orthopedic appliances. While local production comprises mostly low-technology products and prostheses, electrocardiogram monitors and surgical equipment are produced by specialized manufacturers.

Importers are required to have a local representative licensed by the Ministry of Health to distribute medical devices. Product registration is no longer required for CE-marked devices, following implementation of the medical devices directives, but importers must obtain a certificate of compliance from the Turkish Institute of Standards (TSE) before their devices may be introduced to the Turkish market.

While there appear to be few restrictions to imports of CE-marked medical devices which are freely circulated in the EU, medical device manufacturers outside the EU have experienced problems in gaining access to the Turkish market. In particular, there have been reports of additional requirements for manufacturers without a Free Sales Certificate (Form A.TR-1) which establishes that goods are

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freely allowed to be sold to Turkey within the scope of the customs agreement between the EU and Turkey. According to the US advanced medical technology trade association, AdvaMed, manufacturers without a valid A.TR-1 form must submit a CE mark certificate, a Declaration of Conformity and labels and instruction manuals in Turkish in order to export medical devices to Turkey. Some manufacturers have experienced problems with acceptance of CE conformity certification by non-EU companies or Notified Bodies. Imports of CE-marked medical devices which are not freely circulated in the EU may also be subject to inspection by the TSE at the import stage.

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Concern has also been raised that under the new import regime, CE-marked products receive preferential treatment. Imports of medical devices of US origin that are approved by the Food and Drug Administration but do not possess a CE mark are "nearly impossible", according to AdvaMed in a submission to the US Department of Commerce on foreign trade barriers.

**Language Requirements for Medical Devices**

Labeling and Instructions for Use must be Turkish and at least one other language (English, French or German are preferred). Following introduction of the CE compliance procedure, the need to display the TSE (Turkish Institute of Standards) symbol on packaging is no longer required. Documentation for medical devices imported from outside the EU must be in Turkish, whereas for CE-marked products originating in the EU there is a six-month period of grace in which to provide the documents in Turkish, according to the European medical technology manufacturers association, Eucomed.

**Useful Contacts**

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