E-health services: a new era

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E-health services are proving increasingly popular; but many questions remain to be answered before their use becomes mainstream, including in relation to their scope, safety and regulation.

Scope and aim

The World Health Organisation has defined 'e-health' as the provision of health resources and healthcare through electronic means. The objectives of e-health services are to increase the efficiency of healthcare services by reducing costs and saving time.

In this regard, the management of chronic diseases is the first priority, as most health expenditure is spent on treating chronic diseases, while most deaths are also caused by such diseases. Reducing the number of related deaths while simultaneously reducing related government expenditure would be a laudable achievement, and it seems that e-health services could play a vital role in realising this goal.

As an example, imagine a patient with hypertension who can take her blood pressure at home, using a device which transmits the results directly to her doctor. The doctor can see the results instantly on his computer screen and can thus monitor and manage the disease more swiftly, cheaply and comprehensively. There is no need for the patient to visit the surgery for routine monitoring, which saves on the costs of an appointment; the patient and doctor both save time; and the patient will be less nervous at home, leading to more accurate results. It is thus evident that a chronic disease such as hypertension could be more successfully managed through e-health services. The same holds true of other chronic diseases, such as diabetes.

E-health services are already in use in the Turkish private sector; but as yet this use is not sufficiently widespread. In recognition of the importance of e-health services, the

Ministry of Health prepared an e-health strategy within the scope of its Health Reform Programme initiated back in 2003. This provided for the development of more complex IT systems that, among other things, would:

- enable Ministry of Health resources to be recorded in a way that allowed for more efficient planning and management;
- allow patients to make appointments online;
- establish an online database containing data from hospitals, laboratories and family physicians, and facilitate the preparation of reports supporting decisions on treatment methods;
- facilitate e-prescriptions;
- establish a database for healthcare suppliers; and
- track pharmaceuticals in the distribution chain online.

Although these systems have been operational for some time, public healthcare institutions have not yet begun to use e-health services to monitor chronic diseases in the way outlined above. One reason for this may be insufficient technical understanding of such systems. Another may be a perception that as yet, there is no specific law regulating e-health services. However, this is not true, since the existing laws and regulations do regulate the provision of such services.

Applicable rules

It is clear from a study of the Medical Device Regulation - which is in line with EU Directives 93/42/EC and 2007/47/EC - that IT systems and measurement devices which facilitate the management of chronic diseases fall within its scope of application. Among other things, it provides as follows:

> "*Medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological,*

immunological or metabolic means, but which may be assisted in its function by such means."

It is clear from this definition that IT systems and measurement devices used in e-health services qualify as medical devices and are thus subject to the Medical Device Regulation. The Regulation on Active Implantable Medical Devices (which is in line with EU Directive 90/385/EEC, as amended by EU Directive 2007/47/EC) and the Regulation on *In Vitro* Diagnostic Medical Devices (in line with EU Directive 98/79/EC) also apply.

The Medical Device Regulation sets out the minimum standards for a medical device, from manufacture to market. As the authority which is competent to enforce the regulation, the Ministry of Health's Institution of Pharmaceutical and Medical Devices plays a significant role throughout this process.

Article 6 of the Medical Device Regulation states that devices meeting the essential requirements and/or bearing a CE mark should not be prevented from entering he Turkish market, and that the Ministry of Health should impose no additional requirements on them. Article 14 provides that the manufacturers or, if incorporated outside the borders of Turkey, their authorised distributors must register themselves and their medical devices with the Turkish National Databank for Pharmaceuticals and Medical Devices (TITUBB) of the Ministry of Health. No medical device can be marketed within Turkey without being registered in this online system.

TITUBB is similar to the European Databank on Medical Devices, although it has a wider scope of application. TITUBB is used by both the Ministry of Health and the Social Security Institution, and as a tool for public tenders.

Most recently, the Regulation on the Sale, Advertisement and Promotion of Medical Devices came into force upon publication in the *Official Gazette* on May 15 2004. Pursuant to the regulation, any natural or legal person engaged in the sale or commercial distribution of medical devices must be licensed as a sales centre.

It is clear that e-health services may be provided within this regulatory environment.

Comment

E-health services appear to be a promising solution to the need to treat chronic diseases more efficiently, in order to reduce both mortality rates and government expenditure. Given that Turkey has a population of around 80 million and a regulatory framework that is in line with EU law, the market represents significant opportunities for investors from both the IT and health sectors.

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