Registry for Medical Devices: An e-Health Infrastructure for Needs Assessment, Procurement and Management of Medical Devices

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ABSTRACT

Through the past two decades numerous efforts were undertaken towards a digital convergence in the Greek National Healthcare system. E-Health in Greece was initially perceived and developed locally (per healthcare institution) without accrediting the capability of digital technology. This together with the lack of a unified coding and classification system for medical devices not only created system interoperability failures, but also procurement, financial and BIT management issues. Registry of medical devices is a web based application, which has been developed by the National Evaluation Center of Quality & Technology in Health to fill the existing gap and is continuously updated during the last five years in close collaboration with medical device's market and healthcare professionals. Today the Registry is in a mature phase and ready for widespread use. By this way, it is possible to conduct electronic auctions widely, gained complete and accurate picture of the types, quantities and prices of products and mainly made possible the real needs assessment and early planning.

Keywords: Codification, Common Specifications, e-Auctions, e-Health Infrastructures, Management, Medical Devices, Monitoring, Needs Assessment, Planning, Price Observatory

INTRODUCTION

During the last decade, biomedical technology and medical devices are proved to be a crucial factor in healthcare (Pallikarakis & Moore, 2007; Iakovidis et al., 2007). An essential requirement for the healthcare environment, where the free movement of medical devices is a substantial part of world trade, is the attainment of the highest possible level of patient safety, through strict certification criteria, rules and limitations on medical devices released in the European Market. The introduction of the EU New Approach Directives (MDD93/42/EEC, IVDD 98/79/EEC and AIMDD 90/385/EEC) has stated the legal framework for medical

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device certification and circulation in EEU and highlighted the need of a common reference platform. On this common platform, medical devices could be correctly identified, and all the related data could safely be exchanged both between the EU member states for certification or vigilance issues (Notified Bodies, Competent Authorities, manufacturers, suppliers, healthcare organizations, hospitals, etc.) and other international bodies/markets, (bilateral mutual recognition agreements have been set up by the European Union with many countries, each incorporating the exchange of regulatory information).

The National Legislation for medical supplies in the Greek public healthcare sector addresses the legal framework for healthcare procurement (Law 3580/2007). According to the Law 3580/2007 a Greek registry of approved medical Devices and approved suppliers had to be developed, maintained and function as a source database for market monitoring, procurement, management and strategic planning of medical devices in Greece. “Registry of Medical Devices” is a web application which has been developed to confront the infrastructure requirements derived from EU Directives and National Legislation, in terms of recording, classification, management, strategic planning, procurement and market monitoring of medical devices available, or potentially available, in the Greek market. It is addressed to all practitioners of Health, including Public and Private Health Infrastructure, specifically procurement and I.T. services in healthcare, medical device suppliers and manufacturers, as well as the overall public.

EKAPTY’s contribution focuses on e-Health infrastructure by expressing solutions, depicting efficient methodologies and by producing software applications that simplify and rationalize procedures (See Figure 1). Transparency, effectiveness and re-establishment are the main axis in which the design and implementation of the proposed solutions were politically and technically supported on.

The three pillar applications of e-Health promoted by EKAPTY include:

1. A registry for medical devices;
2. A software tool for the production of specifications of medical devices;
3. A healthcare needs estimation system.

Figure 1. EKAPTY’s envision of e-Health
Pre-Implementation Case Studies Evaluating Workflow and Informatics Challenges in Private Primary Care Clinics for Electronic Medical Record Implementation

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