IMPORTANCE OF IMPLEMENTATION OF A SYSTEM FOR EVALUATION OF MEDICAL TECHNOLOGIES

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Although there is no standard definition of health technology assessment (HTA) unanimously accepted internationally, three definitions are most commonly used in the programming documents of the specialized agencies in assessing new technologies:
(1) Defined in full, Goodman, 1998: "Health technology assessment refers to any process of review and reporting the properties of a technology, used in the provision of medical services, such as safety, clinical efficacy, indications, costs, cost - effectiveness, at the same time with the economic, social and ethical consequences of its use, intentional or not”.
(2) Synthetic definition of the International Society of Technology Assessment in Health Care: "The systematic appraisal of properties, results and impact of the use of medical technologies”.
(3) The definition proposed by the European network for Health Technology Assessment (EUnetHTA): "Health technology assessment is a multidisciplinary process that summarizes medical, social, economic and ethical issues related to the use of medical technology in a systematic, transparent, impartial and robust manner. The purpose of HTA is to provide informational support to formulate effective, safe health policies".

The essential conditions to build a system where health technology assessment participates in decision-making are described as follows:
1. Developing an objective mechanism to assist in the formulation of health policies and resource allocation in the health system;
2. The existence of available information which result from the evaluation of health technologies;
3. A high demand of the involved structures to be provided with such information;
4. Effective offer of human, material and organizational resources that can meet the expressed demand and provide the information resulting from health technology assessment.

Health technology assessment, as a tool for decision support, has been used increasingly more intense in Europe in the last 25 years. The first organization of health technology assessment agency founded in Europe was SBU - Sweden 1987, followed by NICE UK, 1995-1999, IQWiG Germany in 2005, Hungary in 2002, Poland 2005/2008. For the development and implementation of HTA system at EU level were carried out several projects:
- EUR-ASSESS (1994-1996);
- HTA Europe (1997-1999);
- ECHTA/ ECAHI (The European Collaboration for Health Technology Assessment / The European Collaboration for Health Interventions, 1999-2001);
- EUnetHTA (European Network for Health Technology Assessment, 2006-2008);
- Currently - extension of EUnetHTA project (EUnetHTA Collaboration), whose aim is to create an effective network of ETM- type of institutions in Europe.

In order to create new HTM- type organizational structures in Europe, EUnetHTA has developed a series of recommendations, namely the establishment of central authority in HTM field - National Agencies for Health Technology Assessment, with more responsibilities:
- Implementation of EU policies in the HTM area at national level;
- Legal mandate to coordinate HTM activities;
- Setting priorities for HTM drafting documents;
- Creating a national platform for the exchange of information regarding ETM;
- Feedback for local ETM research structures;

- Drafting ETM documents in a multidisciplinary context;
- Providing formal links with health policies;
- Participation in international networks.

The personnel responsible for carrying out the evaluation activities (i.e. staff with authority for team leadership, auditing, technical expertise, execution / evaluation of tests, making / assessment of technical inspections / examinations, analysis / file verification related to the product, decision making on product conformity) by applying standard EN ISO 13485: 2012 must meet minimum the criteria contained in Table I.

Table I. Requirements for competence of personnel

Personnel Knowledge / skills	Auditor	Personnel which analysis the audit reports and makes decisions	Expert in technical fields	Personnel which leads the program
Knowledge of general practices of a quality management system	X	X	X	X
Knowing the intended use for medical devices			X	
Knowing the risks associated with medical device			X	
Knowledge of relevant product standards for evaluation			X	
Knowledge of technology / business activity specific to medical devices	X	X	X	X
Knowledge of products, processes and customer organization	X	X	X	X

A well-structured system of health technology assessment will enable the health system:
- The timely introduction of proven technologies that bring significant benefits in terms of health;
- Removal of technologies which did not prove efficacy, evidence-based;
- Monitoring the effectiveness, safety, efficiency and impact of medical technologies after their introduction in the health system;
- Use of resources for the health system on the principle of efficiency, so as to achieve a better state of health for the entire population.

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