PP137 Regional Process For Planning Medical Equipment Procurement In Italy

AUTHORS:

Mario Fregonara Medici (m.fregonaramedici@maggioreosp.novara.it), Stefania Bellelli, Luciano Villarboito, Michela Pepe

INTRODUCTION:

An appropriate governance of the installed equipment base, by defining replacements strategies and programming introductions of innovative Biomedical Technologies (BT), has direct effects on the efficiency and effectiveness of health systems. An effective health technology management is of paramount importance for providing safe, high quality and innovative care with the constraint of health-care budgets, safeguarding equity, access and choice principles. Data from the regional BT information flow show that, compared to the gold standard (1), the North Region of Italy has about 15 percent less of large medical equipment younger than 5 years and about 15 percent more of equipment older than 10 years.

METHODS:

In order to draw a unified path of BT procurement processes, in 2013 and 2014 regional regulations (2,3) were enacted. Each Public Hospital and Local Health Authorities (ASRs) defined a plan (PLTB) containing, regardless of the form of procurement and type of funding, all BT requests for a value greater than EUR40,000 distinguished in replacement/new acquisition/upgrade, innovative acquisition and donations. Requests of BT have to obtain the authorization by the Regional Healthcare Authority Commission (GTB), in compliance with defined criteria, including financial and sustainability aspects, after the evaluation of the Regional Clinical Engineering Commission (GIC) supported by IRES, Health Technology Assessment and Management research group.

RESULTS:

Over the years 2014 and 2015, the ASRs submitted 491 BT requests, of which 87 percent were replacement/new acquisition/upgrade, 9 percent innovative acquisition and 4 percent donations. Altogether 26 percent of these instances were urgent and 2 percent were unique BT on the market. Sixteen percent of requests for replacement/new acquisition/upgrade of BT related to large medical equipment with mean age of 13.3 years, 2 percent regarded innovative BT with average age of 8.4 years and 48 percent widespread technologies with mean age of 15.6 years.

CONCLUSIONS:

The limitations in investments deriving from being a Region in "Recovery Plan", have originated an absence of BT programming, as shown in PLTB by the prevalence of requests for the replacement management of obsolete equipment with inadequate performance, high machine downtimes and elevated maintenance costs.

REFERENCES:

1. Cocir Medical Imaging Equipment Age Profile & Density, Edition 2016.

2. D.G.R. n. 36–6480 del 07/10/2013 "Istituzione di un Piano Regionale delle Tecnologie Biomediche (PRTB) e costituzione di una Commissione Governo delle Tecnologie Biomediche (GTB) per la valutazione e l'approvazione delle richieste di apparecchiature ed attrezzature delle ASR".

3. D.D. n. 299 del 11/04/2014 "Approvazione del regolamento per la redazione del Piano Regionale delle Tecnologie Biomediche (PRTB)".

PP138 Italian Medicines Agency Registries Distribution By Managed Entry Agreements And By Anatomical Therapeutic Area

AUTHORS:

Gabriele Vittoria (Gabriele.vittoria@roche.com), Antonio Fascì, Matteo Ferrario, Giovanni Giuliani

https://doi.org/10.1017/S0266462317002872 Published online by Cambridge University Press

INTRODUCTION:

In a budget constrained environment characterized by an increasing number of high-cost medicines, manufacturers need to demonstrate that their drugs can provide value-for-money. In this complex environment Managed Entry Agreements (MEAs) have been developed with the aim of sharing the risk between the National Health Service (NHS) and manufacturers (1). The objective of this analysis was to identify a correlation between Anatomical Therapeutic Chemical Classification (ATC) and different type of agreements assigned taking into consideration the distribution of Italian Medicines Agency registries by ATC and by kind of agreement negotiated (financial or performance based) (2).

METHODS:

This analysis takes into account all drugs under monitoring AIFA registries in place in Italy from 2006. For each registry included in the analysis it was collected the status of the registry (active, closed or incoming), the disease area that the registry covers and the monitored drugs with or without an associated Managed Entry Agreements. Considering the high weight of oncology drugs, a sub-analysis was done to investigate registries distribution for each specific form of cancer.

RESULTS:

The majority of drugs monitored are under a registry with no associated risk sharing agreement according to AIFA (60 percent). For what concerned monitored drugs with an associated agreement, performance-based agreement is the most diffused type of MEA. In terms of therapeutic area involved in the monitoring registries activity, oncology was the most common area. Financial based agreements characterize principally medicines used for Leukemia and Hepatitis C, whereas drugs administrated for Melanoma, Breast and Ovarian Cancer and Ophthalmology diseases follow performance based agreements.

CONCLUSIONS:

MEAs represent a way to guarantee a sustainable access for innovative medicines. It is proven that oncology products are most likely to have a MEA since they represent some of the most expensive drugs launched in recent years. From this study appear a correlation between the therapeutic disease area of the monitored drugs and MEA assigned by AIFA which is influenced also by other factors like budget impact, risk-benefit ratio and the presence of appropriate endpoints to evaluate the treatment response.

REFERENCES:

1.Italian Medicines Agency Website - Monitoring Registries Section (http://www.agenziafarmaco.gov.it/it/content/lista-aggiornata-dei-nuovi-registri)

2. Garattini L, Casadei G. Risk sharing agreements: What lessons from Italy? *Int J Technol Assess Health Care*. 2011;1;3-6.

PP141 Legal Governance: How Does Law Circumscribe The Social Role Of Health Technology Assessment?

AUTHORS:

Louise Bernier (louise.bernier@usherbrooke.ca), Georges-Auguste Legault, Charles-Etienne Daniel, Suzanne Kocsis Bédard, Jean-Pierre Béland, Christian Bellemare, Pierre Dagenais, Hubert Gagnon, Monelle Parent, Johane Patenaude

INTRODUCTION:

One of the barriers of integrating ethics in Health Technology Assessment (HTA) relates to the social role of HTA (1). The aim of this study is to provide a better understanding of the way by which law circumscribes the social role of HTA. Our hypothesis: HTA's social role is embedded within a mixed governance based on *hard law* and *soft law*.

METHODS:

Three HTA agencies were conveniently selected for our study: Haute Autorité de santé (HAS) (France), National

https://doi.org/10.1017/S0266462317002872 Published online by Cambridge University Press