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.

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

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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

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Institute for Health and Care Excellence (NICE) (United Kingdom) and Institut national d'excellence en santé et en services sociaux (INESSS) (Québec, Canada). Our analysis of the legal, administrative and procedural documents relating to the existence and assessment processes of these three agencies is guided by the following criteria:

1. The normative strength of the documents (categories of hard law or soft law) (2)
2. The definition of the agencies' social role (1)
3. The integration of ethics in the agencies' mandate.

RESULTS:

Hard law contributes to establish a general mandate and some legal legitimacy for these agencies. Soft law, grounded in the HTA producers' practices, plays a major role in the legal governance of HTA. Our results demonstrate that these agencies existing practices seem to circumscribe their social role further than their constitutive laws. In this context, social actors become responsible to define, structure and operationalize the implementation of HTA.

In addition, the legal framework (hard law) through which HTA unfolds does not clearly support its structural and social role. Despite existing legal frameworks, the normative legitimacy of HTA is not entirely established, as it depends on soft law. Taken altogether, this maintains a persisting conceptual vagueness in HTA governance.

CONCLUSIONS:

The social role of HTA should be defined either through modifying existing legislations (hard law) or through harmonization of the agencies internal policies and regulations (soft law). Such legal initiatives would help clarify the aims of HTA evaluations: assessments (scientific) or appraisal (value-laden), and therefore give a clearer indication on how best to integrate ethics in HTA.

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PP142 A Mental Health Hospital-based Health Technology Assessment In Quebec, Canada: Structure And Products

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INTRODUCTION:

Our Hospital-based Health Technology Assessment unit (HB-HTA) was founded in 2011 following the nomination of Louis-H. Lafontaine hospital as the Montreal University Mental Health Institute (IUSMM). From the beginning, the HB-HTA has been supporting and advising the Chief Executive Officer of IUSMM in the decision-making process concerning the implementation of new technologies and practices in mental health. Since 2015, the HB-HTA is part of the East of Montreal Regional Integrated Health and Social Services Centre (CIUSSS de l'Est-de-l'Île de Montréal), continuing to support decisions in mental health. Currently, the HB-HTA unit is nested in the Quality, Performance and Ethics department.

METHODS:

Formed by a coordinator, a scientific advisor and a manager, the HB-HTA team plans, organizes and sets up the evaluation activities. The unit benefits from the support of a Steering Committee which consists of representatives of clinical, administrative and research directions, as well as of health users and families. This committee determine the strategic orientation of the HB-HTA unit, prioritize the projects, approves the evaluation products and gives indications on the knowledge transfer process.

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