**Introduction.** The specificities of non-pharmaceuticals can require adapting classical health technology assessment (HTA) methodologies and developing additional regional approaches to support decision-making processes. However, little information exists regarding the explicit approaches used in different countries. The aim of this work is to provide an overview of the role and activities of the Galician HTA agency (avalia-t, Spain) regarding assessment, appraisal and continued evaluation across the whole life cycle of non-pharmaceutical technologies.

**Methods.** In depth review and analysis of the activities undertaken by avalia-t during the past five years to support the introduction and appropriate use of non-pharmaceutical health care technologies at the regional level.

**Results.** A multidisciplinary Commission judges the added value of new non-pharmaceuticals and establishes the indications and conditions for use. HTAs, which are mandatory for all relevant technologies, rely on the best available evidence on safety and effectiveness but also provide fit for purpose contextualized information based on organizational data and administrative registers. Interaction with multidisciplinary stakeholders is commonly needed to complement the evidence base (ad hoc working groups, face to face discussions), and post-launch studies can be implemented to analyze the utilization and results in real world practice. Performance indicators and other HTA based products can also be required to ensure the quality of health care (e.g., appropriate use indications, quality indicators, evidence based patient information). In addition, technical and scientific advice/support can be provided at different decision levels of the health organization to promote the quality of care and appropriate use of technologies (e.g., regional mental health program, suicide management strategy, bariatric surgery surveillance registry).

**Conclusions.** Rigorous, comprehensive and systematic processes for supporting non-pharmaceutical technology adoption and implementation are required. Although it is acknowledged that core information does not differ substantially within countries, contextualized information is recognized as essential for establishing the conditions for use at the regional level.

## PP30 Do Conditional Regulatory Pathways Affect Health Technology Assessment Recommendations?

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**Introduction.** In an effort to expedite the approval of drugs treating serious illnesses or addressing unmet medical need, conditional approvals have been used by the European Medicines Agency. In this study, the effects of conditional approvals were investigated in terms of health technology assessment (HTA) recommendations and timing in Europe.

**Methods.** First HTA recommendations of new active substances (NASs) issued between 2015 and 2017 were collected from the National Institute for Health and Care Excellence (England), Haute Autorité de Santé (France), Institute for Quality and Efficiency in Health Care (Germany), Scottish Medicine Consortium (Scotland) and Tandvårds-Läkemedelförmånsverket (Sweden). The HTA recommendations were then classified into the following categories: positive, positive with restrictions, negative and multiple and if the regulatory approval pathway had been standard or conditional.

**Results.** Of this cohort of NASs that received an HTA recommendation, eight of 56 in England, 12 of 83 in France, 11 of 77 in Germany, nine of 58 in Scotland and four of 49 in Sweden were approved via a conditional review. Generally, except in England, there were a higher proportion of positive first recommendations for conditional approvals when compared to standard approvals, with Germany showing the largest proportional difference (43 percent) between the two pathways and also a faster time to recommendation. This may relate to the proportion of conditional assessments that were orphan medicines. With the exception of Germany, the time taken from regulatory approval to first HTA recommendation for products with conditional approvals is higher than those for standard approvals, with the largest difference seen in Sweden (241 days longer).

**Conclusions.** Conditionally approved NASs showed a variable HTA outcome; although there was generally a higher proportion of positive recommendations thus enabling more likely access in conditional approvals, the timing from regulatory approval to HTA recommendation was longer compared with standard approvals. This warrants a better understanding of the factors and uncertainties underlying these recommendations, supporting timely access of NASs with conditional approval.

## PP31 Medical Device Regulation: What Is New?

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**Introduction.** In 2017, the European Union (EU) commission released the final versions of the Medical Device Regulation (MDR) and In-vitro Diagnostic Device Regulation. These regulations will replace the EU directives (Medical Device Directive [MDD], In-vitro Diagnostic Device [IVDD], and Active Implantable Medical Device [AIMD]). EU regulations are effective in all EU countries at date of publication. In contrast, the EU directives must be implemented in national law first.

**Methods.** Guidelines and respective legislation, consultation results and methods/medical device (MD) evaluations were reviewed and analyzed. Decision criteria and reasoning, assessment outcomes and potential impact on price negotiations were the main aspects for comparison.

**Results.** Manufacturers have to be aware of the importance of clinical data for demonstrating the compliance of their products. This applies both to the approval of the products and the "post-market activities" and particularly to the "post-market clinical follow-up" for which requirements for Class I and II products need to be further developed. The MDR requires manufacturers to collect clinical data before and after approval, which could lead to excessive documentation requirements. The term "sufficient clinical data" from the MDR is unclear. A functional Eudamed specification is necessary, which enables an automated

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