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?

Jesmine Cai (jcai@cirsci.org), Tina Wang, Neil McAuslane and Lawrence Liberti

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?

Ilse-Barbara Oelze (ilse-barbara.oelze@certara.com), Kurt Neeser and Elvira Müller

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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processing of relevant data. A stronger involvement in the evaluation process is needed as well as more transparency in the Joint Federal Committee (G-BA) and faster evaluation processes.

Conclusions. The MDR increases the burden especially for small businesses, and it is doubtable that the ultimate goal – improving patient safety – will be achieved. The increased demands and rising costs of the new EU MDR and bottlenecks at Notified Bodies can be a risk for the MD industry. Due to the general reduction in the remuneration for services with a high proportion of technical services, it is feared that products will be withdrawn from the market for economic reasons or that they will not be marketed.

PP32 Joint Early Dialogs Between Medical Device Regulation and Health Technology Assessment

Petra Schnell-Inderst (petra.schnell-inderst@umit.at) and Claudia Wild

Introduction. In Europe, the new Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) that entered into force 2017 will have to be applied until 2020 and 2022, respectively. Under the old regulation, there was a large gap between evidence requirements for market approval and market access for high risk (class IIb and III) medical devices (MD). The MDR/IVDR will require appropriate clinical investigations for these MD classes. Despite the different purpose of market approval and surveillance and reimbursement decisions, there are possible synergies with regard to evidence generation, for example, design of pivotal trials and post-launch evidence generation with observational data. In the MDR, early scientific advice can be provided by expert panels of the European Commission if requested by MD developers. For medicinal products, the European network for Health Technology Assessment (EUnetHTA) has established joint early dialogs (JED) of HTA agencies with the European Medicines Agency and manufacturers. A similar approach might be possible with the Medical Device Coordination Group (MDCG). The objective was to explore possible synergies for JED with the MDCG and EUnetHTA.

Methods. In 2018, EUnetHTA established a task force for HTA and MDR/IVDR. A workshop, which will explore possible synergies and activities on JED as well as the viewpoints of stakeholders will be held in May 2019. Participants will be Directorate-Generals GROW (Internal Market, Industry, Entrepreneurship and SME) and SANTE (Health and Food Safety), EUnetHTA members assessing MD, representatives of national competent authorities, Team Notified Bodies, MedTech Europe, patient representatives and academia.

Results. A report on the presentations, the results of the discussion, and next steps in a possible collaboration will be presented.

Conclusions. Joint early scientific advice to manufacturers on the European level for evidence generation by HTA agencies and the MDCG has the potential to streamline evidence generation in the life cycle of high risk MD.

PP34 Costs Of Healthcare-Associated Infections In Latin America

Ângela Bagattini (angelabagattini@gmail.com), Martha Martinez-Silveira, Ana Zara, Valeska Stempliuk and Cristiana Toscano

Introduction. Healthcare-associated infections (HAI) are among the most common preventable health adverse event, associated with significant burden globally. Limited data on HAI costs in lower and middle-income countries is available. The aim of this study is to assess the cost, additional length-of-stay (LOS) and extra-mortality of HAI in the Latin American and Caribbean (LAC) Region.

Methods. We searched Medline/PubMed, Embase, Web of Science, Lilacs, Cochrane, National Health Service Economic Evaluation Database, Centre for Reviews and Dissemination, EconLit, and gray literature published in any language without restriction of date till July 2017. We included observational studies addressing the outcomes of interest, in which hospitalized patients with HAI are compared to those without HAI. The following study designs were included: quasi-experimental, controlled before-after, prospective and retrospective comparative cohort, case-control, and cross-sectional studies. We considered the following HAI-sites: surgical site infections (SSI), catheter-associated urinary-tract infections (CA-UTI), ventilator-associated pneumonia (VAP), and central line-associated bloodstream infection (CLA-BSI), as well as cross-infection (CI). Screening of citations, data extraction, and risk of bias assessment were conducted in duplicate by independent reviewers, according to the study protocol registered on PROSPERO. Reported costs were converted to USD considering official exchange rates.

Results. We identified 4,339 citations. After removing duplicates, a total of 3,029 citations were screened for eligibility. A total of 87 studies from 17 countries were included. The majority (27.4 percent) reported on VAP, followed by CLA-BSI (21.2 percent), SSI (16.4 percent), and CA-UTI (14.4 percent). Most studies (46.7 percent) reported on incremental LOS, with an average of 14.8 days (range 0.9-49 days). Costs were reported by 25 percent of studies, with average incremental costs of USD 3,460 (range 49-12,155). Average extra-mortality of 15.6 percent (range -2.8-45.2 percent) was reported by 12.6 percent of studies.

Conclusions. Available evidence from the LAC Region reports significant economic burden of HAI. This information will be useful for cost-effectiveness analysis of interventions aimed at reducing HAI economic and health burden.

PP35 Valuing Intersectoral Costs And Benefits Of Interventions

Ruben Drost (r.drost@maastrichtuniversity.nl), Aggie Paulus, Dirk Ruwaard and Silvia Evers

Introduction. There is a lack of knowledge about methods for valuing health intervention-related costs and monetary benefits in the education and criminal justice sectors, also known as 'intersectoral costs and benefits' (ICBs). The objective of this study was

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