Methods: Publicly available information on EUnetHTA JAs for individual drugs were identified along with the associated appraisal by NICE, SMC, TLV, HAS, AIFA, SMC, NCPE, ZIN, Medicinradet, AOTM and NOMA (to 12/06/2019). HTA recommendation rates and time to positive appraisal were compared between comparative clinical efficacy (CCE) markets (HAS and Medicinradet) and other (non-CCE) markets (cost-effectiveness or budget impact payer archetypes) ***Results:*** Eight EUnetHTA JAs were identified, 5/8 were for oncology indications and 2/8 were orphan drugs. Forty-one corresponding national HTA appraisals were identified, ten of which were produced by a CCE market (HAS: seven; Medicinradet: three). Of these 7/10 (70%) received a positive appraisal, which did not significantly differ from non-CCE markets 20/31 (65%). CCE-appraised products had a significantly lower mean delay from EC-approval to national HTA publication in comparison to non-CCE markets (223 days and 324 days respectively; p=0.025) ***Conclusions:*** To date, drugs appraised under EUnetHTA JAs have been assessed in a shorter time by CCE markets in comparison to those appraised by non-CCE markets with a similar rate of positive appraisal. This may reflect a greater alignment between the JA clinical framework to CCE market HTA decision-drivers than the non-CCE markets or, may rather reflect natural assessment timelines of the HTA bodies involved. If the pan-clinical HTA proposals come to fruition, their impact may be limited by economic evaluations representing the primary focus of many payer bodies.

PNS245
SNAPSHOT OF EARLY ACCESS PROGRAMMES IN PORTUGAL: A NEW ACCESS HURDLE?

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Objectives: The current regulatory framework of the National Health Technology System (SiNATS) determines that access to new hospital drugs (marketing authorization after September 2017) might be granted before concluding the Health Technology Assessment (HTA) exclusively through early access programmes (EAP), conditional on the lack of therapeutic alternatives and the risk of immediate death or severe complications to patients. EAP conditions imply free-of-charge supply during the expected legal duration of the HTA process (210 days). The aim of this research was to perform a quantitative and qualitative point analysis of EAP appraisals in Portugal. ***Methods:*** The list of published EAP on INFARMED's online database was reviewed on 1st June 2019. Variables collected: target population, therapeutic area, orphan drug status, number of patients enrolled, appraisal outcome and date. Logistic regression models were implemented to determine the influence of therapeutic area and orphan drug status on appraisal outcome. ***Results:*** A total of 37 EAP submissions were recorded, 28 are active EAP while 9 (24%) were rejected. The odds of rejection were estimated to be statistically significant higher for oncology drugs, compared to other therapeutic areas (OR=14.4, p-value=0.018). Furthermore, a non-significant trend towards lower rejection odds was observed for orphan drugs (OR=0.33; p-value=0.21). EAP rejections have been especially noticeable since November 2018, with 45% of submissions being rejected in this period (n=9/20). A considerably higher rejection rate was also observed for oncology drugs (n=8/9, 89%). At the time of the analysis, there were 630 patients under EAP in Portugal. The mean duration for active EAP is 253 days, with some being active for up to 543 days. ***Conclusions:*** A substantial proportion of submitted EAP have been rejected, with significant differences between therapeutic areas. Delays in the HTA process might be extending the duration of EAP, and ultimately generating inadvertent expenditure and compromising drug access.

PNS246
EMA & G-BA - A COMPARISON OF TIME LIMITATIONS OF EUROPEAN MARKETING AUTHORIZATIONS AND GERMAN ADDED BENEFIT ASSESSMENTS FOR NEW PHARMACEUTICALS.

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Objectives: When authorizing new pharmaceuticals, the European Medicines Agency (EMA) can issue limitations on marketing authorizations. The Federal Joint Committee (G-BA) as the German Health Technology Assessment (HTA) institution decides on limitations within the early benefit assessment. This research aims to determine whether there is a correlation between the limitations of EMA and G-BA. ***Methods:*** A quantitative evaluation comparing EMA and G-BA decisions was conducted regarding the reasons and duration. As a data basis, the EMA's published *List of medicinal products under additional monitoring* as of 22 February 2019 was used and all authorizations from the following categories were assessed: Conditional Marketing Authorization (CMA), Authorization Under Exceptional Circumstances (AUEC), Additional Monitoring (AM), Post-Authorization Safety Study (PASS). Information on six former CMAs was also used. Following this approach, all 436 early benefit assessment cases until 3 March 2019 have been assessed for G-BA limitations and linked with the respective EMA rationale. ***Results:*** The descriptive analysis shows that CMAs issued by the EMA also received a limitation with similar reasons by the G-BA with a probability of 88 %. In contrast, EMA authorizations with the status AUEC, PASS, or AM have only led to a limitation by the G-BA in 17 %. Limitations of the G-BA are on average 8.7 months shorter than the duration of CMAs from the EMA. Temporal limitations issued by the G-BA for cases without EMA limitations have mostly been justified by missing data to prove an additional benefit over the appropriate comparator but not with respect to safety or efficacy data. ***Conclusions:*** This analysis illustrates that the national German HTA institution decides in a similar way like the international institution EMA. Though ultimately these findings do not suggest that having no restrictions after the authorization process of the EMA results in the same outcome with the G-BA.

PNS247
THE IMPLICATIONS OF EUROPEAN JOINT CLINICAL ASSESSMENT FOR MEMBER STATE PRICING & MARKET ACCESS

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Objectives: In January 2018, the European Commission proposed a new mandatory clinical efficacy assessment to be facilitated at the EU level for use by Member State HTA authorities as part of national or regional HTA processes. Following amendments to the proposal in the European parliament, implementation is now being discussed in the European Council. The objective of this research is to determine requirements for the practical implementation of the Joint Clinical Assessment into national level pricing and market access processes and implications for patient access and uptake for new medicines. ***Methods:*** An in-depth online consultation was undertaken with a representative sample of former HTA and budget holding stakeholders from across Member States, to determine the implications of the mandatory European Joint Clinical Assessment for national HTA processes, timelines, evidence requirements and pricing agreements. ***Results:*** Whilst the potential for a central EU assessment of clinical benefit to improve efficiency, reduce duplication and accelerate patient access is recognised, considerable uncertainties remain regarding the value and implementation of the assessment reports at the national level. Priority issues for national HTA stakeholders are ensuring accurate representation of the burden of disease, the assessment of incremental benefit vs. a nationally relevant comparator, and ensuring definitions of 'patient relevant endpoints' and acceptable clinical study designs align with currently accepted standards. Under the framework for the Joint Clinical Assessment, voluntary collaboration between member states to undertake pricing negotiations is also predicted to increase. ***Conclusions:*** Mandatory European Joint Clinical Assessment represents a significant opportunity to improve the efficiency of European HTA processes and accelerate patient access to new medicines. In order for key benefits to be realised, the value of the methodologies and standards for evidence assessment must be recognised and agreed at Member State level to directly support the efficiency, scope and quality of national level decision making.

PNS248
DOES THE EVALUATION OF THE FRENCH TRANSPARENCY COMMITTEE (TC) ON DRUG EFFECTIVENESS HAVE AN IMPACT ON THE HEALTH-ECONOMIC EVALUATION CONDUCTED BY THE FRENCH ECONOMIC AND PUBLIC HEALTH ASSESSMENT COMMITTEE (CEESP)?

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Objectives: Since 2013, CEESP evaluates efficiency of the innovative products having a significant impact on national health expenditures. Thanks to this evaluation, products which obtain an ASMR (improvement in medical benefit) I/III may be eligible for the European price guarantee, if the conditions for efficiency are met. In parallel with the efficiency evaluation, a clinical evaluation is conducted by the TC. The TC evaluation being known before that of CEESP, the objective is to evaluate if the TC opinion has an impact on the CEESP opinion. ***Methods:*** Analysis was conducted with the online database *efficience.heva-heor.com* referencing all French published efficiency opinions. This analysis was performed from December 2014 to June 2019 on 94 efficiency opinions. The analysis focused on first-time registrations and distinguished products according to the ASMR level obtained (I/III vs IV/V). Then, different items were analyzed: the number of major objections, the reason of these major objections, and finally, efficiency and price conclusions. ***Results:*** Among these opinions, 51 concerned new products that claimed an ASMR I/III in all their indications, 37 have obtained an ASMR IV/V and 17 an ASMR I/III. Products with ASMR I/III have fewer major objections than those with ASMR IV/V (35% vs 54%) and have fewer negative conclusions on efficiency (18% vs 47%). However, price conclusions are more often negative for products with ASMR I/III (55% vs 23% for products with ASMR IV/V). Ultimately, among products with ASMR I/III, almost half have a positive efficiency opinion (demonstrated efficiency and no negative price conclusion), versus only a quarter of products with ASMR IV/V. ***Conclusions:*** The CEESP is usually consistent with the opinion of the TC on the conclusions reached (fewer negative conclusions on efficiency for products with ASMR I/III); nevertheless, the CEESP makes more comments on the price of products that have obtained ASMR I/III.

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HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENTS IN EUROPE AND NORTH AMERICA SYSTEMATIC REVIEW

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