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Methods: Digital therapeutics (DTx) are rarely differentiated from other digital health technologies (DHTs) such as telemedicine and connected care. Submissions in NICEDMTS and G-BA Diga-directed processes allow the identification of DHTs. Interventions were classified as DTx based on the Digital Therapeutics Alliance definition. Results: In France, DTx are assessed by CNEDMTS, using the same process as for all other medical devices. Most DHTs monitored cardiovascular conditions using implantable devices (RFID). Of those that met the DTx definition (2%), CNEDMTS concluded one intervention had insufficient evidence, one provided additional moderate benefit and one provided minor additional benefit. In May 2020, Germany introduced a reimbursement process specific to DHTs, via BfArM. Of the assessments completed, 30% had achieved reimbursement, 7% had a reimbursement outcome, and 63% of applications were withdrawn. All reimbursed products met the DTx definition; most were psychiatry interventions (53%). 29% of reimbursed products achieved permanent listing on the DiGa directory and demonstrated an improvement of health status. In 2020, NICE established a pilot project for assessing DHTs in the UK; medical technology Zio XT was the first product assessed using this framework. Assessments of 2 DTx are currently in progress (Sleepio and myCOPD). A targeted search also identified NICE advice (a form of evidence summary rather than formal reimbursement assessment) for 14 psychiatry DTx. Conclusions: Germany has reimbursed the most DTx, reflecting the alignment between the DTx definition and BfArM’s assessment criteria for DGA products. France has assessed very few DTx and the assessment of DTx by NICE is less well defined than in France or Germany. The assessment routes in these two countries are expected to evolve and become more distinct as DTx become more common.

POSC252 CURRENT LEVEL OF PATIENT ENGAGEMENT IN HTA AGENCIES
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Objectives: The aim of this study is to analyze current patient involvement in health technology assessments (HTAs) in the European, US and Canadian HTA agencies. Methods: A systematic literature review of articles, published in English between 2016 and 2021 on HTA and patient engagement, has been conducted. Results: A total of 19 articles out of 45, identified through a systematic literature review, were included. It was found that two key sets of reasons for involving patients in HTAs are generally cited in the literature: 1) transparency, legitimacy, and fairness in decision-making and, 2) patients’ evidentiary contributions, as they have first-hand experiential knowledge. There are two different and complementary ways for patient involvement in HTAs: through consultation and/or collaboration. Although patient engagement in HTAs is growing, there is substantial variety in the level of patient engagement across the HTA agencies. Some agencies have well-established patient roles in their HTA processes. Examples of those are CADTH in Canada, in which patients have voting rights, and NICE in the UK and SMC in Scotland in which patients provide submissions to the agency and participate in committee meetings. In the US, patient engagement in HTAs has improved considerably in the last few years; however, it has not yet been well implemented. Patient engagement in HTAs has been reported to have several issues, the methodological issues being the most common ones (82%). Conclusions: The level of patient involvement in HTA agencies across the world is heterogeneous and unclear. The integration of patient preferences in HTAs is expected to contribute to better decision making and to increase uptake, adherence, and patient satisfaction. However, there are some methodological and procedural issues, the large number of different issues advocates the overall importance of a multi-stakeholder and holistic approach to the integration of patient preferences in HTAs.

POSC253 ANALYSIS OF RESULT OF EARLY BENEFIT ASSESSMENT AND REIMBURSEMENT PRICE AFTER FREE-PRICING PERIOD IN GERMANY
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Objectives: The outcome of the early benefit assessment process (according to §35a SCGB V) is crucial for the successful launch and commercialization of pharmaceuticals in Germany. We aim to analyze the change in reimbursement price after early benefit assessment for the first non-orphan evaluation of a drug. Methods: In a first step, data from all non-orphan drug AMNOG dossiers evaluated by the Federal Joint Committee (G-BA) between January 2014 until June 2021 were extracted from IQVIA HTA accelerator and the G-BA website and then were analyzed for benefit assessment outcome. Only the first non-orphan evaluation of a drug was considered excluding drugs for which the orphan status was withdrawn. In a second step, data from G-BA assessments between G-BA and G-BA/A between 01.01.2014 and 15.06.2021 were taken from the official German database for drug prices (LAUER-Taxe). In a last step, launch price vs. negotiated reimbursement price or inclusion into a reference price group were investigated and the price development (in %) was then calculated and categorized into growth, decline, no impact. SMC assessments between January 2014 until June 2021 were extracted from IQVIA HTA accelerator and the G-BA website and then were analyzed for benefit assessment outcome. Before and after early benefit assessment were analyzed. Results: In total, n=138 dossiers evaluated by the G-BA fulfilled the inclusion criteria and were included in our analysis. Of these, G-BA decided for no additional benefit in 58.0% (n=80) of the cases, for non-quantifiable in 3.6% (n=5), minor in 14.5% (n=20), considerable in 23.2% (n=32) and major 0.7% (n=1). Concerning the price changes of pharmaceuticals, we found that the most common price change was in the categories between > 20 % to 40 % growth followed by the 0 % to 20 % growth of 30 % of the cases. Conclusions: As in previous analyses, this analysis found no clear relation between G-BA benefit assessment and price development after one year of free pricing.

POSC254 THE IMPACT OF COVID-19 ON EUROPEAN HTA DECISIONS
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Objectives: To investigate the impact of the COVID-19 pandemic on the drug technology assessment (TA) process of European HTA agencies. This study explored changes to routine practice and assessment in response to the pandemic, and assessed the impact of these changes on the number and type of assessments published during this time. Methods: Adaptations to current assessment practices were established for each HTA agency, including timelines where available. TAs published by the National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC), Haute Autorité de Santé (HAS) and Gemeinsame Bundesauschuss (G-BA) during the last 2 years were identified and compared. Results: Initial meeting suspension resulted in the absence of SMC assessments between May and July 2020, with a subsequent phased approach including scope for ‘fast-track to advice’. As part of the phased approach, medicines with the potential to deliver the greatest benefit to patients were prioritised for assessment, although the number of cancer-related assessments remained consistent. NICE published only one assessment per month in March and April 2020, with minimal notable impact on the number of subsequent assessments. Work related to addressing COVID-19 diagnosis, self-care, and therapeutic interventions received the highest priority and was prioritised, and a higher proportion of assessments pertaining to cancer were published following the emergence of COVID-19. HAS initially assigned priority to drugs intended to manage COVID-19 in addition to new TAs or extension of indication assessments in oncology, paediatrics and in serious illness with an urgent medical need; the number of oncology assessments remained consistent following COVID-19 emergence. The reported impact on Germany was minimal; G-BA meetings were held virtually to minimise delays in assessments or pricing negotiations. Conclusions: Despite the individualised approach in response to the challenges of COVID-19, European HTA agencies demonstrated minimal long-term impact and a return to normal drug TA output.

POSC255 EUROPEAN CROSS-COUNTRY COLLABORATIONS: A FOCUS ON JOINT HTA INITIATIVES AND THEIR FUTURE IMPLICATIONS FOR ORPHAN DRUGS
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Objectives: A growing number of European joint health technology Assessment (HTA) initiatives have emerged, driven by an increasing number of high-cost medicines. This research aims to provide an overview of the current cross-country HTA landscape and identify implications for orphan drugs (ODs) undergoing joint HTA. Methods: Five multi-country HTA initiatives (ElInetHTA, FINOSE, BeNeLuxA, Valletta Declaration and FAAP) were selected on their level of establishment and focus on orphan drugs. Information was retrieved via a targeted literature review of healthcare authority websites, peer-reviewed articles, and grey literature. A qualitative analysis across the initiatives compared the scope, objectives, activities, member countries and number of therapies reviewed. Nusinersen, as the first OD to undergo successful joint BeNeLuxA HTA, was selected to extrapolate key learnings. Results: ElInetHTA was identified as the largest collaboration, comprising of thirty countries; FINOSE, BeNeLuxA and FAAP were found to be the smallest, comprising five each, while the Valletta Declaration comprises ten. Amongst the groups, the highest number of joint HTAs was found to be conducted by ElInetHTA. The scope of the health technologies targeted by the collaborations differed, however a focus on high-cost therapies was detected. Nusinersen achieved similar pricing and reimbursement decisions in Belgium and the Netherlands, through BeNeLuxA. The benefit in review speeds varied across markets; the Belgian decision was reached after 13 months (versus 14 months on average for national processes), the Dutch decision was 13 months (versus 9 months). Representatives of BeNeLuxA highlighted Biogen’s willingness to proactively engage with the initiative during the process. Conclusions: Joint HTA initiatives vary in size and activity level, and many groups focus on expensive, innovative medicines. These collaborations could result in more efficient HTA and pricing processes, leading to faster than average reimbursement decisions in some countries. Proactive engagement and collaboration by manufacturers with these groups could support faster patient access to ODs.

POSC256 APPLICATION OF PROGRESS-FREE SURVIVAL AS SURROGATE ENDPOINT FOR OVERALL SURVIVAL IN NICE REVIEWS OF ADVANCED OR METASTATIC CANCER DRUGS
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Objectives: To assess the application of progression-free survival (PSF) as surrogate endpoint for overall survival (OS) within cost-effectiveness models appraised by