OBJECTIVES: Submitting an HTA dossier is a cardinal step in gaining market access for new drugs. While decision making heavily depends on the choice of technology assessment guidelines and the type of HTA submissions are submitted in the last 3 years have scrutinized to identify the key differences across European agencies (AwMSG, CVZ, DQGFS, G-BA, HAS/CPS, NCPE, NICE, SMC, TIVL). Criteria reviewed included the guidelines strictness, and the need of comparative effectiveness, health economic, and budget impact analysis.

RESULTS: The majority of Agencies reviewed (89%) have a well defined template but the outline differs markedly between them. Differences relate to the requested contents (clinical and budgetary outcomes only [33%] vs. a more cost-effectiveness framework [67%], and the perspective from which the evidence is reviewed (societal [17%] versus national health system or statutory health insurance perspective [83%]). Additional differences are the preferred type of economic model (cost utility versus cost per clinical benefit) and budget impact (incremental budget impact versus net costs) and weight given to indirect treatment comparisons when head-to-head studies are lacking.

CONCLUSIONS: Our review illustrates the lack of standardization of the requirements across European HTAs. This renders the development of a GVD easily adaptable to country-specific submissions, a difficult task. Our review suggests that the GVD should be orchestrated around the needs for NICE and implemented with the particularities of the different HTAs.

PHP126 FROM INNOVATION TO MARKET ACCESS: REIMBURSEMENT STRATEGIES OF MEDICAL INDUSTRY IN DUTCH HEALTH CARE
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OBJECTIVES: Health economics and outcomes research (HE&OR) have become increasingly important for Dutch policy makers to decide on the content of the statutory insurance package. Pharmaceutical companies have been well developed in conducting outcomes research and presenting health economics data in order to access the insurance package, and reimbursement for their products. However, HE&OR data are not the only objectives for successful reimbursement strategies. The objective of this study was to analyse reimbursement trajectories in order to unravel factors for successful market access. METHODS: A qualitative, retrospective study have been performed from 2008-2011. Period of study: 1999 -2010. In this partiest. Those goals can easiest be converged on patients' level. Ministry. Our analysis shows that in depth knowledge of Dutch financing scheme patient organizations are being invited to consultations with policy makers and the pharmaceutical companies, scientific associations of physicians, and well-developed patient organizations are being invited to consultations with policy makers and the Ministry. Our analysis shows that in depth knowledge of Dutch financing scheme needs to be accompanied with mutual trust and converging goals of the several parties. Those goals can easiest be converged on patients' level. CONCLUSIONS: Although Dutch policy makers are emphasising HE&OR for accessing the insurance package, our study shows that important arguments for successful market access are institutional trust and converging goals of the several parties and, from January 1, 2012, in-depth knowledge of the Dutch dedicated DRG-system.

PHP127 REIMBURSEMENT OF ORPHAN DRUGS: WHAT IS THE DIFFERENCE?
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OBJECTIVES: Orphan drugs are subject to regulatory and reimbursement regulations that differ with respect to application process and necessary documentation. An orphan drug status granted by the European Commission gives marketing exemption and a time period for EU 10 years with approval. Reimbursement hurdles are also supposedly lower for orphan drugs in Europe than usually. METHODS: Definition and assessment process of orphan drugs for reimbursement were reviewed and analyzed. Differences to other drugs are outlined and reimbursement decisions for orphan drugs are presented. RESULTS: The G-BA implemented in 2011 requires that with market access newly approved products demonstrate their innovation through a reimbursement dossier to avoid reference group pricing. For orphan drugs, manufacturers must also submit a dossier but the additional medical benefit is assumed to have been proved by the market authorization itself. Thus proof of additional benefit does need not be provided but information on relevant patient groups and on the extent of this additional benefit. However, if annual sales of an orphan drug within the statutory health insurance exceed 50 million EUR, a full assessment is made. For pitirifonine, the first approved orphan drug under the new law, (Quality and Efficiency in Health Care) declined an additional therapeutic benefit and the G-BA (Joint Federal Committee) did not follow this conclusion in accordance to the law. In Italy pitirifonine was grouped into the lowest reimbursement class. Unlike Germany, Italy has special funds set aside for orphan drugs, France has an early access program, and many countries are struggling with how to create a reimbursement process that reflects the different regulatory provisions for orphans. CONCLUSIONS: Although orphan drugs are often regarded as unquestioned reimbursable, differences in respective processes and assessments exists. Manufacturers are requested to build Market Access arguments carefully and expect challenges in orphan drug indications as well.

PHP128 AMNOG IN YEAR 2: INSIGHTS FROM EARLY BENEFIT ASSESSMENTS IN GERMANY
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OBJECTIVES: In 2011, Germany’s new health care reform (AMNOG) came into effect requiring that with market access newly approved products demonstrate their innovation to avoid reference group pricing. The manufacturer has to submit a dossier proving additional benefit versus the appropriate comparator recommended by the G-BA (Joint Federal Committee). On request of the G-BA, IQWiG (Institute for Quality and Efficiency in Health Care) reviews the dossier and performs the benefit assessment. Manufacturers, associations and experts can present comments and attend a hearing; thereafter the G-BA publishes its final resolution.

METHODS: Benefit assessments and G-BA decisions to date were reviewed and analyzed case by case. Differences between IQWiG and G-BA evaluations are outlined, consequences depicted. RESULTS: Up to now 32 dossiers have been submitted, 19 completed the whole process and further 8 will be finally assessed shortly. About half of the products additional therapeutic benefit was granted allowing price negotiations with the statutory health insurance. Not in all cases did the IQWiG decision for AMNOG’s concept for Erlotinib (a Cancer Drug) follow the G-BA’s recommendation. For some drugs additional therapeutic benefit was granted allowing price negotiations with the statutory health insurance. Not in all cases did the IQWiG decision for AMNOG’s concept for Erlotinib (an Orphan Drug) follow the G-BA’s recommendation. For some drugs additional therapeutic benefit was granted allowing price negotiations with the statutory health insurance. Not in all cases did the IQWiG decision for AMNOG’s concept for Erlotinib (a Cancer Drug) follow the G-BA’s recommendation.

CONCLUSIONS: Although in its second year, AMNOG is still a learning process for all parties involved. Before initiating a dossier it is crucial to investigate possible pitfalls around dossier development. New questions will emerge when it comes to the assessment of drugs already on the market as it is now planned for DPP-4 inhibitors.

PHP130 GUIDELINES WITHOUT GUIDANCE: THE CASE OF EPIDEMIOLOGICAL DATA BEYOND CLINICAL TRIALS
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OBJECTIVES: Exploring the use of population-level epidemiological data (i) within the reimbursement decision making process, (ii) identifying recommendations and requirements on that data, and (iii) investigating the role of that data for reimbursement decisions as stated in pharmacoeconomic guidelines. METHODS: We piloted a comparative review of all national pharmacoeconomic guidelines published in English (N=26 out of 33) available through the ISPOR Website http://www.ispor.org/EPGuidelines/index.asp. RESULTS: The use of population-level epidemiological data was addressed by 20 guidelines.16 mentioned the use for economic evaluations, 4 (additionally) for budget impact analyses, and 4 (also) for broader technology assessments. 14 guidelines provided explicit recommenda-