made available to patients. The objective of this abstract is to highlight the difference of data requirements between the EMA and some of the main HTA bodies, and the subsequent outcomes in terms of access and reimbursement decisions. **METHODS:** The list of medicines under CA status was downloaded on March 16th 2015 from the EMA website.2 For each medicine, advice from the National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC), National Authority for Health (HAS) and Federal Joint Committee (GBA) was taken from the agencies' websites.3 The HTA outcomes were measured from final recommendation in the UK, the medical benefit (SMR) and improvement in medical benefit (ASMR) scores in France and the level of additional benefit in Germany. Medicines approved after March 2014 (n = 3) and vaccines (n = 2) were excluded. **RESULTS:** 77% of the selected medicines had at least one unfavourable HTA outcome (defined as no or restricted recommendation in the UK, SMR lower than substantial and/or ASMR V in France, no or unquantifiable additional benefit in Germany). 50% had a majority of unfavourable HTA outcomes. **CONCLUSIONS:** Although the EMA seems to have accelerated patient access to selected medicines, it does not actually translate into patient accessibility as regulators and payers have a different perception on the benefits these medicines offer. Greater alignment between regulators and payers is needed for patients. 1Article 14(7) of Regulation (EC) No 726/2004; 2http://www.ema.europa.eu/ema/; 3http://www.has-sante.fr/portail/jcms/r_1500918/en/les-avis-sur-les-medicaments, http://www.english.g-ba.de/, https://www.nice.org.uk/, https://www.scottishmedicines.org.uk/Home

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A HANDBOOK AND A TOOLKIT FOR HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT

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OBJECTIVES: Hospitals need a formalized system to introduce new health technologies. Hospital-based HTA (HB-HTA) units can provide relevant and timely information to decision makers. However, to date no comprehensive body of knowledge of current practices and tools exists to guide how to set up these units in hospitals. AdHopHTA, a European research project funded by the FP7, aims to gather information and knowledge and develop these tools. Therefore, our objectives are to present the handbook and web-based toolkit for HB-HTA developed by the AdHopHTA project, which aims to guide and facilitate the setting-up and the daily work (e.g. assessments) of an HB-HTA unit. **METHODS:** AdHopHTA has used a multi-method approach to develop the content of the handbook and toolkit including 6 literature reviews, 107 face-to-face surveys, 40 case studies, 1 large-scale survey, 1 focus group, 1 Delphi process, 1 validation workshop and several Steering and Advisory Committee meetings. In total 375 people from 20 different countries have provided their input. **RESULTS:** The handbook presents the informational needs and organizational models of HB-HTA units in Europe. It also describes the positive impact of HB-HTA in the adoption of new health technologies in hospitals and how to create a comprehensive HTA ecosystem through the interaction between national or regional HTA organizations and HB-HTA units. 15 guiding principles for good practices in HB-HTA are also presented using current examples from existing HB-HTA units. The Toolkit is built based on these guiding principles. It consists of practical guidance grouped into four dimensions (the assessment process; leadership, strategy and partnerships; resources and and impact). It includes proposed solutions to potential problems as well as specific tools (e.g. AdHopHTA mini-HTA template) for each dimension. **CONCLUSIONS:** The AdHopHTA Handbook and Toolkit are support instruments for designing, setting-up and running HB-HTA units.

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THE CEESP ECONOMIC EVALUATION: CAN CLINICAL EFFICACY AND COST-EFFECTIVENESS CO-EXIST IN FRANCE

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OBJECTIVES: The Commission for Economic Evaluations and Public Health (Commission Evaluation Economique et de Santé Publique, (CEESP)) has been conducting health economic evaluations since 2008. Due to continued economic pressure, as of October 2013, manufacturers are required to submit an economic evaluation to the CEESP under certain conditions, in addition to the Commission de Transparence's existing clinical assessment. The objective of this analysis was to gain a better understanding of the drivers of positive and negative CEESP decisions. **METHODS:** All publically available CEESP decisions were retrieved from the agency's website in April 2015. The CEESP evaluates submissions against the HAS' pharmacoeconomic guidelines, in which areas of weakness are identified through a system of "reserves" rather than a strict ICER threshold. Data was extracted to determine the number of and rationale for minor, important, and major reserves awarded by CEESP to the manufacturer's submission, as well as accepted incremental cost-effectiveness ratios. **RESULTS:** According to HAS's methodological guide for economic evaluations, cost-effectiveness should be considered alongside clinical efficacy. At the time of analysis, four CEEPS appraisals were publically available. 50% of submissions had ICERs above 100,000 EUR per QALY gained, and based on findings to date, no firm ICER threshold was apparent. 50% of submissions were found to have minor, important, as well as major reserves. Our analysis revealed 5 key factors to improve the chance of a positive CEESP review: (1) A clearly presented analysis with a validated model structure; (2) a submission that satisfies the HAS guidelines; (3) a proper justification of all model inputs and assumptions; (4) an appropriate comparator; (5) a consideration of the "national factor". **CONCLUSIONS:** CEESP appraisal has only recently emerged as a market access requirement in France; continuous monitoring will be needed to better understand positive and negative drivers of decisions.

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CONSUMER INTEREST IN ADOPTING AN ELECTRONIC HEALTH RECORD (EHR) MOBILE APPLICATION BASED ON THE RISK THAT IDENTIFIABLE INFORMATION IS LEAKED

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OBJECTIVES: This study was designed to understand consumer interest in a mobile application designed to allow individuals to view their personal health record on a mobile device, and to share their health records with someone else if they choose. As a secondary objective, this study evaluated the likelihood of consumers to use the device based on the varying risk of a leak of their identifiable information (risk tolerance). **METHODS:** A representative (U.S.) sample of 1,000 adults completed an online survey about their interest in an EHR mobile application. Interest in the application was elucidating using a 7-point Likert scale and a standard gamble (SG) exercise. **RESULTS:** Prior to any indication of a potential privacy risk, 31% of consumers indicate they would be very likely to download an EHR mobile application (rated 6 or 7 on 7-point Likert scale; 4.0 mean). Nearly half (44%) of those who do not expect to use the app indicate they have privacy concerns. Based on the SG, only 50% report they would download the mobile application if there was a 95% chance their data was completely secure. Expected use of the application declines rapidly; 39% would use it if there was a 90% chance their data was completely secure and 31% would use it if there was an 85% chance their data was completely secure. Only 3% are still interested in the application with only a 5% chance their data was completely secure. **CONCLUSIONS:** There is a sizeable market for EHR mobile applications. Up to half of consumers report interest in using an EHR mobile application; and yet, there are important data concerns. Particularly given large-scale data breaches of large organizations, it will be critical for developers to quell fears of potential users of a data leak.

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AN ANALYSIS OF GERMAN G-BA ADDED BENEFIT ASSESSMENT DECISIONS USING THE WORLD HEALTH ORGANIZATION DALY FRAMEWORK

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OBJECTIVES: Since January 2011, the German G-BA has evaluated new drugs on their degree of added benefit versus a comparator therapy. We used disease-specific Disability Adjusted Life Years (DALYs), reported by the World Health Organization (WHO) as the sum of Years of Life Lost from mortality (YLL) plus Years Lost due to Disability (YLD), to help explain G-BA benefit assessment decisions. **METHODS:** EMA-approved drugs (January 2010-June 2015) were identified from European Public Assessment Reports (EPARs) and cross-referenced with the G-BA website to create an analysis set of drugs that have received benefit assessment ratings. Drugs with EMA orphan-drug designation were excluded. We defined Added Benefit (AB) as drugs that received G-BA ratings of "considerable", "low", or "unquantifiable" benefit in any patient subgroup, and No Added Benefit (NAB) as drugs only receiving ratings of "no additional benefit" and "inferior". Using WHO-reported German 2012 DALYs, proportions of YLLs and YLDs for each drug's lead indication were calculated: Drugs for diseases in which YLLs >75% of the DALY were defined as High Mortality Drugs (HMD); drugs for all other diseases were Low Mortality Drugs (LMD). We then predicted the odds of receiving AB versus NAB based on this new metric. SPSS was used to perform Fisher's exact test and to generate Odds Ratios (OR). Sensitivity analyses were performed on the %YLL threshold definition. **RESULTS:** From 373 EPARs, we identified 73 non-orphan drugs receiving G-BA benefit assessment ratings, 58 of which had matched DALY data for the lead indication. Of these 58 drugs, 35 were indicated for HMDs while 23 had LMD indications. 30 of 35 (86%) HMDs received an AB rating while only 4 of 23 (17%) LMDs received an AB rating ($p<0.001$, OR: 28.6). **CONCLUSIONS:** Our analysis suggests that in Germany there may be a demonstrated and predictable bias for drugs for fatal diseases.

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ROMANIA'S NEW HTA SYSTEM: WHAT PROGRESS HAVE INNOVATIVE DRUGS MADE UNDER THE POINTS-BASED SYSTEM SO FAR?

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OBJECTIVES: To assess the progress of a large group of innovative drugs evaluated recently under the HTA system introduced in Romania in 2014, which is the mechanism now used to reach decisions on which new medicines are included on the reimbursement list. **METHODS:** A systematic study of the HTA decisions already taken by the department for health technology assessment of the Romanian drug agency was undertaken, to ascertain the number of medicines / indications approved for unconditional reimbursement (not requiring cost-volume contracts), conditional reimbursement (requiring cost-volume contracts) and those not qualifying for reimbursement. Patterns were sought and identified among those drugs / indications which are awarded higher and lower points scores. **RESULTS:** Of the 144 HTA decisions, considering only originator medicines and their indications, there have been 23 recommendations for unconditional reimbursement, 51 recommendations for conditional reimbursement, and 70 recommendations for exclusion from reimbursement. Among the therapeutic areas and drug types in which unconditional reimbursement decisions are frequent are new oral anticoagulant drugs and type-2 diabetes drugs. Many older originator medicines have tended to receive lower points scores, not qualifying for reimbursement. **CONCLUSIONS:** The HTA points system in Romania is in its early stages but already some patterns are emerging from the combination of criteria used to accumulate points – including decisions by western European HTA bodies, the number of EU member states in which a drug is reimbursed, and the impact on the budget of the Romanian health insurer. With major legislative transformations underway in Romania's pharmaceutical pricing and reimbursement system, the real