Supplementary table 1. List of Investigated Countries and EUnetHTA Partners Involved in This Study

Countries	EUnetHTA Partners
Austria	Ludwig Boltzmann Institute of Health Technology Assessment (LBI@HTA)
Australia	None
Belgium	None
Canada (Ontario)	None
Cyprus	Ministry of Health
Denmark	Danish Centre for Health Technology Assessment (DACEHTA) Centre for Applied Health Services Research and Technology Assessment (CAST)
Estonia	University of Tartu Department of Public Health
France	French National Authority for Health (HAS) Committee for Evaluation and Diffusion of Innovative Technologies (CEDIT)
Finland	Finnish Office for Health Technology Assessment (FinOHTA)
Germany	German Institute of Medical Documentation and Information (DIMDI) Institute for Social Medicine, Medical University of Lübeck Competence Center for Clinical Trials, University of Bremen
Ireland	Health Information and Quality Authority (HIQA)
Italy	Regional Agency for Health and Social Care (ASSR) for Emilia-Romagna *Universita Cattolica del Sacro Cuore*, Faculty of Economics, HTA Unit *Instituto Superiore di Sanita* (ISS) on behalf of the It-Net-HTA group *Regione Veneto*, Health and Social Planning Department
Latvia	Health Statistics and Medical Technologies State Agency
Netherlands	Health Care Insurance Board (CVZ)
Norway	Norwegian Knowledge Centre (NOKC)
Poland	Agency for Health Technology Assessment in Poland (AHTAPOL)
Portugal	Institute of Molecular Medicine (IMM)
Slovenia	Institute of Public Health of the Republic of Slovenia (IPHRS)
Spain	National Health Technologies Assessment Agency (AETS) Andalusian Health Technologies Assessment Agency (AETSA) Basque Office for Health Technology Assessment (Osteba) Galician Health Technologies Assessment Agency (Avalia-t)
Sweden	Swedish Council on Technology Assessment in Health Care (SBU)
Switzerland	Swiss Network for Health Technology Assessment (SNHTA)
England/Wales	National Horizon Scanning Center (NHSC) National Institute for Health and Clinical Excellence (NICE)
US	Center for Medical Technology Policy (CMTP)

Supplementary table 2. Established AEG Mechanisms Associated with Marketing Approval Decisions

	Conditional marketing approval	**Post marketing studies** †#
Objectives	To confirm preliminary results on safety and efficacy	To collect key data that are not a prerequisite for marketing approval: • to confirm the benefit/risk ratio under real-life or experimental conditions • to investigate safety concerns identified at the pre-marketing stage or during the marketing authorization procedure, under real-life conditions
Applicability	• Drugs for the treatment, prevention or diagnosis of serious life-threatening or debilitating diseases or for use in emergency situations • The public health benefit of immediate access overweighs the risk due to the lack of data	• Drugs giving rise to concerns about efficacy/effectiveness in real-life • Drugs exhibiting observed safety concerns • Drugs without any major safety concerns, but for which routine pharmacovigilance is not appropriate • Drugs for which additional data are required in target populations not covered in clinical trials
Preliminary evidence requirement	Preliminary scientific evidence indicates positive benefit/risk ratio	Evidence suggests that the benefit/risk ratio is positive, but efficacy/safety concerns arise on real-life use or are suggested by the preliminary evidence
Data collection requirements	Systematic (clinical trials)	Systematic under experimental conditions (clinical trials in specified populations) and real-life conditions (registries; pharmacoepidemiological studies, comparative observational studies, drug use studies, sentinel sites, individual follow-up of patients…)
Data collection schedule	Agreed timeframe	
Funding for data collection	Applicant	Applicant/holder or public institution
Schedule of reassessment	Annually	When data available (end of study)
Expected consequence	Should lead to the granting of a "conventional" marketing approval	May lead to a revised marketing authorization (or suspension or withdrawal)
Decision-making authority	EMEA-EC/National medicine agencies/ Ministry of Health	EMEA-EC/National medicine agencies/Ministry of Health
Countries	European countries (EMEA), Belgium, Canada, Denmark, France, Germany, Italy, Spain	European countries (EMEA)*, Australia, Belgium, Canada, Finland, France, Germany, Italy, Latvia, Netherlands, Portugal, Spain, US

* European risk management plan (RMP) may be complemented by a national RMP; †Include active

SUPPLEMENTARY FIGURE

Supplementary figure 1. General policy framework to describe AEG mechanisms for promising health technologies and time-points in their life cycle when AEG mechanisms are applicable.