reimbursement decisions. Our objective was to evaluate the lag between a drug’s FDA approval and the publication of the first CUA evaluating the product. METHODS: We used the FDA’s database to identify newly approved drugs from 2000-2002. For each drug, we searched the Tufts Medical Center Cost-Effectiveness Analysis Registry and the NHS Economic Evaluation Database for CUA evaluating the drug, in the same order as the FDA approved. We included drugs with a corresponding CUA in our dataset. When multiple CUA s were available, we included the CUA with the earliest publication date. We used multivariate regression to determine factors associated with time to CUA publication (years). Independent variables included drug approval year, study funder, i.e., whether the CUA was supported by industry, and whether the FDA assigned the drug priority review status. RESULTS: One hundred and fifty-six (45.6%) drugs in our sample had a corresponding CUA. Average time to CUA publication was 4 years (standard deviation 2.3 years). We divided drug approvals into three time intervals: 2000-2002 (mean time to CUA publication=3.1, SD=4.2), 2003-2006 (mean=3.9, SD=3.8), 2007-2010 (mean=2.4, SD=0.9). The results from chained Fisher and unchained counterparts were similar (25% vs. 26% difference between 2000-2002 vs. 2007-2010; p<0.001). Source of study support and FDA priority review status were not significantly associated with time to publication. CONCLUSIONS: Not only clinical benefit and cost-effectiveness but the disease severity, the uncertainty of evidence and reimbursement in other countries were also considered in the reimbursement decision making. Not only clinical benefit and cost-effectiveness were required for reimbursement despite ICER was high. Submissions which had low uncertainty in cost-effectiveness were rejected. Submissions which demonstrated superiority or non-inferiority in clinical benefit, 79% of 325 submissions comparing four high-impact regions Europe, United States, Australia and Canada. METHODS: First, we performed a literature search about the authorization and reimbursement processes of high-risk medical devices in Europe. This research aims at exploring the authorization and reimbursement processes and the associated evidence requirements, comparing four high-impact regions Europe, United States, Australia and Canada. RESULTS: The four high-impact regions displayed clear differences in the four high-impact regions related to the approval and reimbursement processes. All seven devices have been approved in Europe, three in Australia, one in the United States, and one in Canada. Currently none of the seven devices is recommended for reimbursement in the four high-impact regions. CONCLUSIONS: Looking at the difference in evidence requirements, more harmonization, transparency and specific regulations are needed worldwide for the authorization and reimbursement of high-risk medical devices to ensure a high-quality and safe provision.

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**INFORMATION REQUIREMENTS COMPARING THE AUTHORIZATION AND REIMBURSEMENT PROCESSES OF HIGH-RISK MEDICAL DEVICES – THE EUROPEAN SITUATION**

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**OBJECTIVES:** In the last decade awareness has been raised due to unsafe and dangerous medical devices entering the European market, putting patient safety at stake. Consequently, evidence requirements may not be enough to ensure a high-quality and safe provision of medical devices in Europe. This research aims at exploring the authorization and reimbursement processes and the associated evidence requirements, comparing four high-impact regions Europe, United States, Australia and Canada. RESULTS: First, we performed a literature search about the authorization and reimbursement processes in the four high-impact regions. Second, seven high-risk medical devices with current authorization and reimbursement status were assessed. Information was extracted from publicly available summaries, from PubMed, and from the clinical trial database (clincialtrial.gov), supplemented by the worldwideweb. RESULTS: The evidence required for the authorization and reimbursement processes clearly differed in the four high-impact regions. All seven devices have been approved in Europe, three in Australia, one in the United States, and one in Canada. Currently none of the seven devices is recommended for reimbursement in the four high-impact regions. CONCLUSIONS: Looking at the difference in evidence requirements, more harmonization, transparency and specific regulations are needed worldwide for the authorization and reimbursement of high-risk medical devices to ensure a high-quality and safe provision.