PP70 Comparison Of Approval Dates Of New Substances Between The U.S. Food And Drug Administration And The European Medicines Agency

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Introduction: Early access to innovative medications is a key factor for the quality of medical care. We investigated differences in approval dates of new active substances between the U.S. and Europe and a potential connection with company headquarter location.
Methods: Data of new active substances (no generics, biosimilars, and hybrids) approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) from 1 January 2018 to 29 November 2023 were retrieved from FDA and EMA websites. We calculated the time difference between the drug approval dates between the agencies. We also retrieved the location of the headquarters of pharmaceutical companies.
Results: Since 2018, 390 medicines were approved by FDA or EMA: 113 (29.0%) only by FDA versus 40 (10.3%) only by EMA, and 237 (60.8%) by both. Approval of 32.1 percent of medicines occurred within six months. Fifty-seven percent were approved more than six months earlier by FDA and 11.0 percent more than six months earlier by EMA. Overall, 45.6 percent of the headquarters are in Europe and 44.1 percent are in North America. For medicines approved by FDA only, 63.7 percent of headquarters are in North America and 26.5 percent are in Europe. This is reversed for medicines approved by EMA only. For substances approved by both, 50.6 percent of headquarters are in Europe and 39.2 percent are in North America.
Conclusions: Almost 30 percent of new medicines approved by FDA within the last five years are not yet approved in Europe whereas only 10 percent are approved by EMA only. There is a tendency for companies with headquarters in North America to seek approval from FDA first. For medicines with approval from both authorities, most companies are primarily located in Europe.

PP71 Organizations Responsible For The Evaluation Of Health Technologies Globally: A Scoping Review

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Introduction: The process of health technology assessment (HTA) is a valuable tool for the pursuit of equitable and sustainable healthcare systems. Various countries have established organizations dedicated to conducting HTAs, adapting such institutions to local healthcare ecosystems. The aim of this study was to evaluate the structure, methods, and processes of organizations responsible for national-level HTAs globally.
Methods: A scoping review was conducted assessing organizations responsible for conducting HTAs for national-level decision-making in any country. Identification of eligible organizations was performed through a review of member organizations of INAHTA, EUnetHTA, RedETSA, and HTAsiaLink networks, as well as organizations evaluated in reviews with a similar scope. For each organization, the following data were searched: country, year of foundation, organizational nature, role in decision-making, funding, technologies assessed, criteria considered for decision-making (such as efficacy and safety, costs, impact on equity, among others), type of economic evaluation, and patient involvement.
Results: We identified 69 organizations, from 56 countries, mainly European (n=39; 56%). Fifty-three (77%) are government-affiliated; most (n=51; 74%) have a consultative role. Public funding is the main funding, and 12 (17%) organizations charge fees for conducting HTA. Technologies assessed include drugs (n=61; 88%), devices (n=47; 68%), and procedures (n=33; 48%). HTA is usually initiated upon request from the manufacturer (n=45; 65%). Patient involvement is not clearly described in 32 organizations (46%); in 29 organizations (42%), the role of patients is to provide information that is considered during decision-making.
Conclusions: Among the evaluated organizations, it is observed that the majority are government-affiliated, have public funding, and play a consultative role. The results of this study serve as an important reference for the development and improvement of organizations responsible for conducting HTAs.

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