at the National Institute of Health, the FDA, and the Physician’s Desk Reference versus 1980-2012. Data were collected by 2 researchers and the MOAs classified as: known, unknown, or hypothesized. Another investigator resolved observed differences. Chi-square tests were used to compare proportions. RESULTS: A total of 816 new drugs (79 BLA and 737 NMEs) were approved by the FDA during the study period. The MOA was known for 95.7% of biologics and 64.4% of NMEs. Known MOA was the Anatomical Therapeutic Chemical (ATC) code with the lowest proportion of known MOA (11.8% known MOA out of 77 approved products). Blood and blood forming organs was the class with the highest proportion of unknown MOAs (92.7%; n=89). The proportion of products with known MOA increased over time from 56.4% (n=202 approvals) in the 1980s to 71.7% (n=265) in the 2000s. No significant differences were observed in terms of known MOA between orphan/non-orphan drugs, marketed/discontinued products, and specialized products. CONCLUSIONS: An important number of drugs did not have a known MOA. In addition, there was great variability in the wording of MOA, especially hypothetical ones. The lack of information and the need to consider standardizing the label with regard to MOA and encourage manufacturers to continue collecting evidence to verify a drug’s MOA after market approval.

PHP35 IMPROVING MEDICAL DEVICE REGULATION: EUROPE AND THE PERSPECTIVE IN THE UNITED STATES

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OBJECTIVES: Recent events in Europe and the US have brought into question the effectiveness of existing regulatory frameworks to ensure the performance, safety, and quality of new medical devices. Given that policymakers are currently exploring ways to reform medical device regulation to address these issues, this study aimed to examine current medical device regulation policies in both jurisdictions, understand outstanding regulatory challenges, and identify ways to improve regulatory practices.

METHODS: The study examined the respective regulatory systems based on a critical review of available, relevant scientific and grey literature. In addition, the websites of national medical device regulatory agencies (e.g., FDA, MHRA, EMA) were reviewed to assess legislative and policy documents.

RESULTS: The review highlighted a number of challenges for medical device regulation in both jurisdictions: 1) finding the right balance between centralized and decentralized regulation; 2) ensuring sufficient evidence to safeguard public health, especially for high-risk devices; 3) implementing mechanisms and incentives for monitoring and evaluating post-market device safety and effectiveness; and 4) providing adequate and transparent information exchange on the benefits and risks of new technologies. To address these issues, European and US policy makers and other stakeholders have implemented various initiatives or are considering their introduction. Specific policies include establishing a more centralized system of regulation in Europe, requiring uniform oversight and evidence requirements across and within European countries; and, use of national and European databases to track and monitor medical devices as well as registries. Where appropriate, the review was informed by the consultation of interested parties, especially for high-risk medical devices.

CONCLUSIONS: Additional actions are needed to ensure high-performing medical device regulation. These include providing sufficient incentives for manufacturers to conduct pre-market clinical studies, making market access conditions more transparent, and creating consistent mechanisms for post-market monitoring. The experience in Europe should be considered when designing new policies or revising existing ones. Further research is needed to inform the development of regulatory strategies that balance the need for a comprehensive and transparent system with the need for effective oversight and efficient decision-making.