Flexible Regulation of Health Technologies: Insights from Financial and Environmental Regulation

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Traditionally, the regulation of new health technologies has followed a stringent and linear process, requiring pharmaceutical and biosciences firms to demonstrate that the health technology meets prespecified safety and efficacy thresholds prior to market entry and reimbursement. Under this traditional command-and-control approach, post-market regulatory assessment occurs infrequently, typically triggered by adverse event reporting or foreign notification requirements. Similarly, reimbursement decision-making has traditionally utilized a one-time binary decision to reimburse the use of the health technology, or not, based on the clinical evidence that exists at the point of the decision. In this traditional regulatory environment, clinical information about the health technology that emerged following either a regulatory or reimbursement decision is not guaranteed to accumulate and impact regulatory and reimbursement decision. The emergence of innovative health technologies, such as precision medicine and gene and cell therapies, have exposed gaps in the conventional regulatory approach. Such innovative health technologies, which often target small patient populations, can risk preclusion from market access and reimbursement because of inherent difficulties collecting sufficient clinical evidence required to support positive regulatory and reimbursement decisions. To promote patient access to innovative health technologies, regulatory and reimbursement bodies have introduced ad hoc mechanisms and regulatory pathways that trade point-in-time decision-making for life-cycle regulation, including conditional decisions and regulatory sandboxes. Conditional decision-making has been proposed and implemented by both regulatory and reimbursement decision-makers to promote earlier patient access and create mechanisms for enhanced post-market evidentiary assessment to make regulatory and reimbursement status more responsive to emerging evidence. Though conditional mechanisms have been utilized for decades, they continue to face criticism for lack of transparency, enforcement, and responsiveness to developing evidence. Regulatory sandboxes, popularized in fintech, allow controlled regulatory experimentation to tailor regulatory frameworks on a case-by-case basis. Under a regulatory sandbox approach, standard regulatory requirements may be waived or amended. The use of regulatory sandboxes to regulate health technologies is still in its infancy, but together with conditional approaches, represent a departure from the traditional command-and-control regulatory style used in drug regulation for the last half a century towards a more flexible regulatory approach. Flexible regulatory approaches have been adopted in other domains, such as finance and energy regulation, to manage and encourage innovation. Eschewing the bright-line rules characteristic of command-and-control approaches, flexible approaches instead relying on nuanced, context-specific regulatory approaches to permit regulatory responsiveness to industry innovation. However, the shift to flexible regulation has not been without challenges. Experience with flexible regulation from finance and environmental regulation provides insight that can be leveraged when designing and implementing flexible regulatory approaches for health technologies to promote an appropriate balance promoting innovation and protecting the public.