Prescriptions for Adaptive Drug Licensing at The System Level

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Introduction

The next generation of treatments is becoming more complicated while also being tailored to smaller portions of the population. As statisticians debate how to fit the future of translational medicine to the "sufficient and well powered" evidence requirement necessary for regulatory clearance, the question of how to accommodate the growing rate of product innovation in the real world remains unanswered. Researchers tackle this topic straight on in a large-scale article. The organisation contends that enabling timely patient access to future therapies necessitates moving beyond a one-dimensional vision of regulatory policy, involving various stakeholders, and conducting continuing risk and benefit assessments across a drug's entire life cycle. Following a global trend of medication approvals being paired with post-licensing data gathering requirements. suggest six real-world transitions needed to take this notion to the next level. A suggested transition from a "single, gated licensing choice" to a "life span management" strategy that would minimise risks through "learning-confirming-(re)licensing" is particularly intriguing. The group even describes a future de facto norm of "adaptive licensing," in which practically all product licences will be constantly tied to clinical practise data. They propose that enhanced mechanisms for generating both randomised and observational assessments of benefit-risk after an initial product licence has been issued are critical to this future.

New approaches to medication and medical device regulatory approval have been proposed, replacing single decision points with periodic or staged evaluation and re-assessment based on a developing evidence basis. These suggestions have been dubbed "progressive" or "adaptive" licencing systems, and are explicitly referred to by words like "staggered approval," "adaptive approval," "progressive licencing," and "progressive authorisation." These new methods' stated goals are to increase patient access to innovation, alleviate clinical ambiguity, ensure real-world efficacy, and improve the health technology development process. Many of these techniques have been created without the participation of Health Technology Assessment (HTA) and coverage bodies (HTA/coverage bodies), who are crucial participants in the management of medication and medical device diffusion. Adaptive techniques to reimbursement decision making have been implemented by HTA/coverage bodies using phrases such as "coverage with evidence development, access with evidence development, and controlled entry." The goals of adaptive licencing and reimbursement methods to decision making overlap significantly, with adaptive reimbursement techniques also attempting to address cost effectiveness uncertainty. While there are parallels between adaptive licencing and coverage methods, there is a growing realisation that technology dissemination is influenced by parties other than HTA/coverage organisations and regulators, such as care providers and health system management, as well as patients. The interplay of various stakeholders and their roles in decision making would thus necessitate careful study for the success of any adaptive strategy. The Health Technology Assessment International (HTAi) Policy Forum has considered adaptive decision-making techniques on multiple occasions, as well as the possibility of aligning HTA evidence criteria with those of related decision-making processes, notably licencing.

Given the growing interest in adaptive licencing and the need for multi-stakeholder input on the subject, the Policy Forum decided to have a discussion on it in February 2014. The goal was to go through recent advancements and talk about general approaches to adaptive decision making for pharmaceuticals and medical devices. The implications of adaptive licencing plans for HTA/coverage bodies were a major topic of discussion.

Consequences for Current Ethical and Legal Standards

Earlier access to medicines with continuous evidence collecting associated to regulatory, HTA/coverage body, and health system demands may provide challenges for existing ethical and legal norms related to care provision and research oversight. Early access to medicines with promise but unknown benefits may increase patients' perceived risk, therefore enough information regarding clinical uncertainty must be provided and informed patient permission secured. Currently, the type of permission obtained from patients is determined by whether the therapy is deemed "research" or "regular usage," and with an adaptive strategy, this border gets blurred. According to one Forum member, this distinction may be interpreted by some as implying that the regulator "assumes a measure of ethical responsibility for the wellbeing of research participants."

Adaptive techniques may also necessitate a greater number of post-market studies to be undertaken concurrently and guided by decision rules that accentuate present patient recruitment concerns. Post-market research, for example, already enhances the need for appropriate informed consent based on an acceptable degree of risk exposure. It may also exacerbate jurisdictional variations in ethical norms. According to one Forum member, definitions of informed consent in certain countries are based on "what would a reasonable patient wish to know," as assessed by a jury of peers, and "what do doctors normally do" in others.

The conversation indicated the need for payers and producers to collaborate more closely with current ethical governance systems (jurisdictional ethics review and consent standards) to help re-define regulations around the use of technology in treatment and research. It is unclear who could best assist this transformation. One possibility is for the regulator, payer(s), patient association(s), or manufacturer to lead the process. For example, the newly announced EMA-led European adaptive licencing trial emphasises the regulator's connection with the clinical, regulatory, ethics oversight, and HTA communities as a catalyst for bringing parties together. The present overlapping legal duties of industry, regulators, payers, those performing clinical research, and those delivering treatment may also need to be reconsidered For example, adaptive approaches challenge the notion of strict legal requirements regarding what public or private insurers must cover in benefit plans for patients. Shifts in legal obligations and provisions for indemnification for non-negligent harm caused by technology may also be necessary. Finally, there may be a need to reassess who is legally liable at various stages along an adaptive route.

Drugs versus Devices

Some of the fundamental challenges highlighted by using adaptive techniques to medical devices are similar to those posed by applying adaptive approaches to pharmaceuticals, but there are significant variances due to the nature of the technology and changes in current regulatory and reimbursement procedures. Many pharmaceuticals are already released in a phased manner an initial indication for one group followed by other indications, which is more commonly planned by product innovators while medical devices are introduced with less formal constraints in many countries. Data gathering by drug vs device maker takes place at distinct stages, with drug firms focusing on pre-market data collecting and device companies focusing on post-market data collection. The formal criteria for evidence will also range between various kinds of devices and may vary depending on jurisdiction. The sorts of research designs that are achievable with devices differ from those that are available with medications, due to difficulties with blinded treatment allocation or appropriate controls in some circumstances.

Furthermore, unlike outpatient medications, decisions or recommendations to utilise devices are not usually determined at the national level and are made in hospitals or local health authorities in many countries. Both sectors have instances of adaptive techniques, but their viewpoints on their growth may differ: for the device sector, this may be viewed as imposing more limits on technological diffusion than already exist, but for medications, it may be viewed as more flexible. This implies that adaptive techniques for drugs and medical devices would need to be created differently, taking into consideration regulatory, HTA/coverage body, and health system characteristics. Designing an adaptable strategy must account for these variances, which may need the development of several adaptive procedures based on the specific requirements of the medical device class. Despite the Forum's detailed discussion of the difficulties raised by medical devices and medications, there will undoubtedly be a greater need for additional debate about the viability of adaptive methods recognising these concerns and maybe discovering others.

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