Regulatory review of new product innovation: Conceptual clarity and future research directions

Abstract

Regulatory review of new product innovation (NPI) has come to dominate contemporary discourse on innovation management. However, there continue to be a lack of clarity on how normative and scientific logics of evaluation combine to influence the regulatory review process. To bring some much-needed clarity, we draw on the diverse literature streams on regulatory reviews and NPI to unpack how the regulatory review process may play out in practice. We then explicate four varieties of regulatory review concerns that frequently affect regulatory decisions: speed and delays, safety and efficacy, cost and uncertainty, and routines. We go further to present eight propositions regarding these concerns to extend our understanding on how they may constitutively influence regulators decisions in articulating the value of NPIs and their potential to shaping innovation trajectories. We conclude by outlining and highlighting rich opportunities for future research.

Keywords: New product innovation, regulatory reviews, routines, cost and uncertainty, safety, speed, and delays

Introduction

New product innovation drives economic growth, improves the welfare of society, underpins firm competitiveness, and remains critical for organisational renewal and survival in today's high velocity business environment (Sarpong and Maclean, 2012; Slater et al., 2014; Donbesuur et al., 2020). Thus, for most firms a successful commercialisation of their innovative products is the lifeblood of their very existence (Miller, 2021). However, the transition of these innovations from the laboratory to the market takes a rather bendy and complex path, as products are required to meet strict regulatory standards and requirements (Foucart & Li, 2021; Shen, 2013; Garber et al., 2004). Regulatory agencies, tasked with the responsibility of effectively conducting technical evaluation of products in order to mitigate safety issues which could otherwise pose danger to public health (Downer, 2011; Olson, 2008; Rindova et al., 2005), subject new products to rigorous scientific scrutiny before granting authorisation to commercialise. These regulatory agencies usurp a repertoire of experts who are considered to be *au courant* with technological trajectories in the new product innovation (NPI) landscape, and whose decision to grant market authorisation confers legitimacy to products in the selection environment,

influences consumers' perception of product quality and thus determines the success of NPIs on the market (Polidoro, 2020; Polidoro, 2013; Bitektine, 2011).

Yet, several studies suggest that the influence of regulatory reviews on innovation is often times less inspiring (Ranchordás, 2015; Prieger, 2008; Kessler and Chakrabarti, 1996). Some scholars contend that regulatory review processes may slow the pace of new product commercialisation thereby delaying profits or competitive advantage which could be accrued to the innovators and restrict consumers' timely access to life-saving products (Grabowski, 2008; Carpenter, 2002). Also, other scholars argue that in direct contrast with the notion that regulatory agencies are at the frontiers of the technological knowledge on which innovations are developed (Rindova et al., 2005; Hargadon and Douglas, 2001), there is a yawning knowledge gap between innovators and regulators about the underlying technology on which NPIs are built (Liberti et al., 2013; Downer, 2010; Carpenter, 2002). As a result, regulators are sometimes ill-informed about the technological trajectories in the innovation landscape and therefore lack suitable evaluation framework for reviewing NPIs (Kuzma and Besley, 2008). An emerging concern in the literature also points to the cognitive effect of routines as a fundamental cause of discrepancies and delays in regulatory review processes and decisions (Polidoro, 2020).

In this paper, we explore varieties of regulatory review concerns that frequently affect regulatory decisions, including speed and delays, safety and efficacy, cost and uncertainty, and routines, to emphasise on how a NPI review process extends beyond the perceived organizing logic of scientific rigour. In this regard, our aim is to offer greater conceptual clarity on how the interplay between normative and scientific logics may influence and define the NPI review process. We embed in our discussions, consideration for the centrality of regulatory evaluations in the innovating firm's NPI development strategies to elucidate on the power of regulatory agencies in shaping both current and future innovations. In this vein, we contribute to the existing literature by, first, providing a comprehensive conceptual framework that links regulatory review concerns to their resultant implication for NPI in order to offer a richer view of regulators' role in articulating the value of new

product innovations to consumers. Second, we provide new insights about the interdependence between regulators and innovators by suggesting that regulatory agencies rely on continuous review of NPI to improve or streamline their evaluation framework. More broadly, by complementing the extant emphasis in the literature on the role of routines in agency adaptation, we contribute to the discourse on regulatory reviews by arguing that cognitive underpinnings of routines may facilitate adaptation of regulatory review framework to respond to the dynamics of the innovation landscape.

The paper proceeds as follows. First, we explain our approach to searching and selecting the relevant literature for our study. Next, we provide a brief discussion on the organising logic of regulatory agencies in reviewing NPI to grant market authorisation and commercialisation. Following this, we unpack specific regulatory issues that cumulatively influence the regulatory review process and decisions. We finish by discussing the main contributions and new opportunities for future research and highlight on the shortcomings in our arguments.

Literature search and selection

The core literature in our review were selected through a keyword search on various online academic database including Web of science, Scopus, JSTOR, Science Direct and Business Source Complete. The following search strings were used to capture the relevant papers: *regulatory review* OR *regulatory evaluation*, *reg* rev** AND *innovation** OR *new product, product review* OR *New product review/evaluation*. The process returned an output of 238 articles which was reduced to 143 after merging and removing duplicates. The multidisciplinary nature of the discourse on regulatory reviews led us to avoid "being too specific to restrict the range of literature that can be covered" (Wee, and Banister, 2016, p. 282), hence the scope of the articles extended beyond the mainstream innovation management journals to include those in economics and medicine disciplines. However, we eschewed from being too general and thus adopted a narrow definition for regulatory review—a sequence of evaluations conducted by regulatory agencies before new product innovations (NPIs) are allowed onto the market. In this regard, 81 articles that did not explicitly used regulatory reviews and product innovation as the main thesis of

their study were excluded from the sample. Although we focused on articles published in peer reviewed journals in order to ensure that the selection process served as a mechanism that prioritises quality, we included 3 book chapters after snowballing bibliographies of the initial list of articles. The inclusion these widely cited book chapters ensured completeness and validity of the selected literature sample and our arguments (Tranfield et al. 2003), as they had made some insightful contributions on regulatory reviews the context of the United States Food and Drugs Authority (FDA). Our analysis of a final literature sample of 65 revealed that the empirical focus of the various scholarly works was predominantly skewed to the pharmaceutical drug industry. Also, several of the literature overlapped in the terms of core arguments but presented subtle differences in their empirical contributions. The analysis progressed to identify some emerging regulatory review concerns from the literature which were then classified based on specific themes of arguments (see table 1).

Insert Table 1 about here

Regulatory review and the logics of evaluation

The series of evaluations that are conducted before new products are allowed onto the market remains the preserve of experts who are perceived to be well-informed about the different technologies driving NPI development (Hargadon and Douglas, 2001; Rindova et al., 2005). In this regard, the scientific testing rules which inform the standards and techniques that are employed in the NPI review process serve as the backdrop against which product reviewers evaluate NPIs. Thus, these scientific frameworks constitute the logics underpinning the criteria for evaluating and granting market authorisation to NPIs (Garud and Rappa, 1994). Also, in the process of reviewing products for market commercialisation regulators may set their evaluation criteria within internationally recognised regulatory standards and requirements, such as the International Organisation for Standardization (ISO) (Manders et al., 2016). This is done to ensure that the focal innovation under review meets responsible innovation standards and enhance penetration of products into other collaborating markets. And although these general standards are often focused on innovation management

guidelines and environmental concerns (Awan et al., 2021; Manders et al., 2016), they serve as the basis for defining and designing the scientific evaluation processes. As summarised in figure 1, the decision-making process for granting market authorisation, which marks the culmination of years of research, design, and development of NPIs, requires that all relevant details on new products undergo rigorous scientific review process in order to ensure that the products meet predefined evaluation standards (Chorniy et al., 2020; McNamee et al., 2017; Downer, 2010). Failure to satisfy these scientific evaluation standards leads to rejection of NPIs and ultimately refusal of market authorisation.

Insert Figure 1 about here

Unpacking the regulatory review concerns

The logics of regulatory decisions, we contend, are not always derived from the scientific evidence and knowledge which serve as the evidential backdrop for granting market authorisation to NPIs (Sherman et al., 2017). There are several other normative and non-scientific based factors that may influence the regulatory review process and may become consequential for the success of NPI on the market. In line with discussions on regulatory reviews in terms these other consequential factors, the extant literature points to some observable and non-observable factors that are widely recognised as the underlying cause of incongruities in regulatory decisions and review time (Gans and Ridley 2013; Regnstrom et al., 2010; Carpenter, 2002). Prominent among these factors are the importance ascribed to NPI, the size and characteristics of the innovating firm, and the social and institutional environment within which innovations are conceived (Hargadon and Douglas, 2001; Ishibashi et al., 2012; Olson, 1997; Dranove and Meltzer, 1994). Cumulatively, these factors may influence regulatory decision, determine the success, and articulate the value of NPIs to the market. On this basis, our core argument here is that there are specific regulatory issues which cumulatively enable (or impede) the sequence of evaluations conducted by regulatory agencies before new products are allowed onto the market. We argue that these concerns do not only shape the organising practices and work of regulators, but also give form to

firms' perceptions of the regulators' power to influence the firms' ability to create and capture value from their innovations (Polidoro, 2020; Blind, 2016; Blind et al., 2017). Against this background, we now explicate four varieties of regulatory review concerns that frequently affect regulatory decisions (figure 2) and provide detailed discussion on each concern.

Insert Figure 2 about here

Speed and delays

The time elapsed between the initial submission of a product for regulatory review and the granting of approval for commercialisation remains, perhaps, the most important concern to both innovators and reviewers (Ellwood et al., 2017; Prieger, 2008; Prieger, 2007). For the innovating firms, the ability to capture first-mover advantage is heavily dependent on the swift delivery of their innovative products to the market (Papachristos and Van de Kaa, 2020; Zhao et al., 2012). Therefore, accelerating all intermediate activities and decisions in the regulatory evaluation process in order to expedite the transition of their NPI from the laboratory to the market is a critical success factor and priority (Kessler and Chakrabarti, 1996; Vesey, 1991). However, this objective is usually not realised, as the regulatory review processes often takes longer than anticipated (Kaitin, 2010). Thus, while political officials may deploy polices to drive regulatory agencies to expedite the evaluation process (Carpenter et al., 2012), financial incentives may alter regulator's responsiveness to a particular industry (Olson, 2000), or the urgent need to satisfy consumer interest may succeed in compelling regulators to expedite the evaluation process (Olson, 1995). That notwithstanding, the decision to speed up the regulatory review process remains within the discretionary remit of the regulator (Carpenter et al., 2012). Consequently, a regulator's decision to protract review processes may potentially lead to a reduction in the present value of NPI, diminish the competitive advantage and profits that may be accrued to the innovating firm, constrain the pace of innovation, and may even distort the incentive to innovate (Prieger, 2007; Carpenter, 2004; Prieger, 2002). Nonetheless, there are several underlying conditions which also suggest that the apparent regulatory delays are unintended. For instance, the upshot of the knowledge

gap between innovators and reviewers is the additional time regulators may require in assessing and extending their understanding of the technology underpinning the NPI under review in order to arrive at a decision (Rosenblatt et al., 2016; Carpenter, 2004). This phenomenon is largely due to the pace at which technologies evolve as well as the complexity and sophistication they come with. Thus, regulators are faced with the challenge to adapt quickly and provide timely reviews for the ever-changing NPI landscape. More so, the absence of credible scientific research, lags in the publication of research findings and weak links between academia and the regulatory agencies often leave regulators incapacitated to make market authorisation decisions with an acceptable level of certainty (Sherman, et al., 2017; Abraham, 2002). As a result, regulatory agencies become inept at evaluating radically NPIs, and are sometimes left with no option but to rely on product innovator to provide some insights into the underlying technology of the NPI in order to swiftly evaluate products (Downer, 2011). Taking this into account, it can be argued that:

> **Proposition 1:** The depth of the knowledge gap between reviewers and innovators about a product's underlying technology(ies) affects the speed of reviews.

Nonetheless, there are some notable efforts that have been made to narrow or even eliminate delays in regulatory review processes, particularly in the pharmaceutical drug industry. Considering the dire need for medical products to combat neglected diseases, the United States Food Drug Administration (FDA), for example, assigns ratings to new therapeutic agents developed for such diseases and categorises them for priority review (Gans and Ridley, 2013; Ridley et al., 2006; Kaitin et al., 1994). Also, in addressing concerns with delays, Prescription Drug User Fee Act (PDUFA) adopted by the FDA to help the provide finance needed to improve infrastructure and hire additional staff to review large clinical data and clear application backlogs (Ono et al., 2005; Reichert et al., 2001; Olson, 2000). These interventions have been noted to be pivotal to improving the FDA's administrative procedures and have facilitated the use of modern technologies to process huge data (Amankwah-Amoah, J., 2016), which in turn has led to reduction in review times (Downing et al., 2012; Ichimaru et al., 2010; DiMasi and Faden, 2009; Olson, 2004). However, given the role of regulator's discretion in the

review process (Carpenter, 2004), there are lingering concerns about incongruities and biases in review times across different products. Some observable and non-observable factors such as firm size, the degree of communication between reviewers and innovating firms, the extent of reviewers' involvement in the new product development process and the importance ascribed to products have been identified to influence the regulator's decision to withhold, approve, or delay NPI commercialisation (Regnstrom et al., 2010; Kaitin and Cairns, 2003; Olson, 1997; Dranove and Meltzer, 1994).

Turning our attention to firms' characteristics, the literature suggest that relatively large multinational firms tend to experience shorter review time and expect favourable decisions (Olson, 1997; Thomas, 1990). These privileges enjoyed such global firms are based on several factors including the availability and readiness of data from previous reviews of products in other collaborating jurisdictions (Ishibashi et al., 2012; Olson, 1997). It is worth noting that regulatory agencies often rely on data from other regions where products have already been reviewed to inform the decision to reject or approve a product for commercialisation (Kaitin and Cairns, 2003; Gieringer, 1985). Thus, earlier submissions and approval of similar products in collaborating regions tend to reduce the number of issues that a product under review need to sift through for approval (Downing and Ross, 2017; Carpenter, 2004; Wrubel et al., 1997). In addition, these large firms often have huge capital to invest in intensive research and development (R&D) which enables them to specialise and capture market niches that regulators may be keen on satisfying and introduce products that meet regulatory requirements (Carpenter 2012; Carpenter, 2004). Furthermore, well-established firms are able to muster their experience of the complex review process to provide all relevant information to regulators and reduce uncertainty about their ability to produce products that are safe and efficacious (Regnstrom et al., 2010; Carpenter, 2004). Also, innovating firms that consult the regulator may gain clarity on regulatory requirements, signal cost of delays to regulators and grant reviewers access to core technological information that are needed to bridge the knowledge gap (Prieger, 2008).

In terms of other factors that contribute to the speed of NPI review process, regulatory agency's sensitivity to social unrest is noted for shaping the operational objectives to meeting market demand and responding to public and political pressures (Carpenter, 2004; Carpenter, 2002; Vogel, 1990). On this concern, Dranove and Meltzer (1994) observed that regulatory review process is expedited for products that are accorded some degree of importance and social value. The recent Covid-19 pandemic, for example, has seen regulatory agencies dropping oil on the wheels of the product evaluation machinery for potential vaccines needed to fight the virus. The Medicines and Health Products Regulatory Agency (MHRA) in the United Kingdom (UK), for instance, adopted a 'rolling review strategy', which involves gathering data for safety checks alongside clinical trials, in order to streamline and expedite market authorisation (MHRA, 2020). This thus emphasise that the importance attached to products which contribute to the humanitarian response to emergencies is a key factor in expediting the evaluation process (Gans and Ridley, 2013; Dranove and Meltzer, 1994). Yet, a keen interest in expediting regulatory review processes and decisions may hold far-reaching adverse consequences for consumers. One could argue that there is no significant relationship between review time and product safety and that reducing review time for product could neither result in adverse effects nor increase the number market withdrawals (Berndt et al., 2005; Friedman et el., 1999). One the contrary, there has been some concerns in the pharmaceutical drug industry about the prevalence of warning labels on most products classified as important medical advances for life-threatening diseases for which the review process was accelerated (Grabowski and Wang, 2008). Thus, we caution that when regulators become known for speed rather than safety, the public may lose out on benefits from efficacious products and this may cause public health havoc (The Economist, 2020; Carpenter, 2012). Overall:

> **Proposition 2**: The speed of regulatory reviews is not only dependent on the swiftness of the product reviewer, but also on a cluster of non-scientific factors that may facilitate access to verified scientific data and attach social value or urgency to the NPI under review.

Safety and efficacy

The most salient justification for the institutionalisation of regulatory reviews is grounded in the notion that new products are not to gain access to the market until safety and efficacy is assured (Haines, 2017; Kumar et al., 2010). This keen interest in safeguarding public health reflects a growing interest in social wellbeing and an increasingly positive attitude toward public safety (Shen et al., 2013; Breckenridge et al., 2011). Thus, as gatekeepers of public safety regulatory agencies subject new products to rigorous scientific evaluation and rely on the resultant evidence to inform their decision to approve or restrict products from commercialising (Downer, 2010; Carpenter, 2002; Olson, 1995). Although gathering compelling data to guarantee safety and efficacy is perhaps the most complicated and time-consuming phase in the review process, this mandate remains the core concern of the product reviewer as it is a necessary condition to mitigate the asymmetrically distributed nature of information between produces or innovators and consumers (Polidoro, 2020; Shen et al., 2013; Downer, 2011; Ono et al., 2005). In the absence of such regulatory reviews, consumers may have to take safety risks by relying on prolonged use of products to ascertain their safety (Rindova et al., 2005). Regulatory reviews therefore remain the only means to restrict the commercialisation and consumption of potentially harmful products. In keeping the public on the alert, regulatory agencies confer approval stamps on products to signal product safety, efficacy, and quality to the market (Polidoro, 2013). As such, the consumer's reliance on regulatory the approval stamps to evaluating and selecting from the variety of available products (Polidoro, 2013; Foucart and Li, 2021) emphasises on the power of regulatory agencies to influence decisions elicited in the market-based selection environment (Polidoro, 2020; Nelson and Winter, 1982). This implies that products that bypass regulatory approval are likely to fail, as they do not have legitimacy in the selection environment (Guo et al., 2014). Therefore:

> **Proposition 3**: As regulatory agencies confer a seal of approval on NPI they guarantee safety and quality products, influence consumer confidence and selection decisions, and determine the legitimacy and success of products on the market.

Although the informational value gained from regulatory reviews is crucial in ensuring that products do not bypass any safety checks or quality assurance, this legitimate call to regulators as

gatekeepers of public safety is sometimes weakened by the need to satisfy and respond to public demand and political pressures (Carpenter, 2004; Olson, 1995). In this sense, reviewers are found juggling political pressure, public interest, and scientific evidence. This poses a fundamental challenge to the reviewer, a conundrum on how to assure the safety and efficacy of products while at the same time providing timely public access to products (Chorniy et al., 2020). There are some notable instances where regulatory agencies, motivated by the objective to protect public health, had faced fierce opposition from consumers due to their decision to delay or restrict product from commercialisation due to unsatisfactory data on safety. One of such incidents is the FDA's attempt to prohibit the use of an artificial sweetener called Saccharin. The decision to ban the product was based on a study conducted by the Health Protection Branch (HPB), which had raised red flags about the damaging effects of consuming the product (Vogel, 1990). However, opposition from both consumers and the business community, coupled with support from the media, resulted in a reversal of the ban. A politically sensitive regulator therefore may succumb to public pressure and limit the number of safety issues that a product needs to sift through for approval (Carpenter, 2004).

However, scholars have observed that advocating for stringent evaluation framework may also lead to high rejection rates of NPI (DiMasi et al., 2010; Kuzma and Besley, 2008). Specifically, in conditions where reviewers do not have a clear and well-defined evaluation framework for products that are built on novel technologies. In this regard, reviewers tend to adopt evaluation standards for other closely related technologies or products as a proxy for deciding on the approval or rejection of the NPI under review (Tait et al., 2021; Tyner and Sadrieh, 2011; Kuzma and Besley, 2008). Further discussing this concern in the context of the US airline industry, Downer (2010) laments that the Federal Aviation Administration (FAA), the regulatory agency which is charged with the responsibility of assessing the reliability and safety of passenger aircraft, sometimes delegates technical evaluations to the innovators who are well-established in the industry and have more tacit knowledge in the prevailing technology. Here, the product evaluator tends to delegate their responsibility to ensure safety to the very institutions whose activities could pose a risk to society. This lack of *ad rem* regulatory

standards and frameworks then breeds uncertainty among end-users concerning the efficiency and reliability of regulatory review processes in ensuring safety and protecting public safety (Arora and Tosti, 2017; Berndt, 2005). Consequently, the regulatory review framework becomes fraught with uncertainties about safety and may result in potentially damaging consequences for NPI in the long term (Gieringer, 1985). Also, an innovating firm's reputation is a significant factor in this situation (Rindova et al., 2005), as firms that are known to the regulator to have high approval rates are at advantage as they may assuage safety and quality uncertainties and precondition regulators to view their radically novel products as efficacious (Carpenter, 2004; Kaitin and Cairns, 2003). As a result, there have been some advocations for an 'informed choice' system which relinquishes the responsibility so evaluate product safety to consumers by tasking the innovators make to all requisite information on products available to consumers in order that they intuitively make a rational choice without regulatory influence (Gans and Ridley, 2013; Gieringer, 1985). However, as the challenges of information asymmetry is yet to see its demise in the existing market conditions this system is bound to be futile.

In keeping with these arguments, we propose that:

> **Proposition 4**: An innovating firm's reputation shapes the regulator's perception about the safety and quality of a product under review, such that when the firm has a record of high (low) regulatory approval rate, the level of uncertainty about safety and quality of product is low (high).

Cost and uncertainty

Turning to the cost associated with regulatory reviews, this concern is perceived to have negative influence on both consumers and innovating firms. For consumers, delays in the regulatory review process may slow access to potentially valuable products. Prolonged approval of products that are of importance to combatting health crises, for example, could also lead to public outrage and social unrest (Gieringer, 1985). For the innovating firms, the stringent, laggard, and complex nature of regulatory review process imposes huge financial cost and uncertainties on their NPI initiatives (Tait et al., 2021). The ever-increasing numbers and complexity of data required for regulatory approval imposes a severe financial burden on innovating firms, and this is leading to the collapse of relatively smaller innovating

firms in the pharmaceutical industry (Rosenblatt et al., 2016; Dimasi et al., 2003; Thomas, 1990). In recent times, several scholars have observed that in addition to loss in early entrant profit and competitive advantage that may be accrued to the innovating firm (Prieger, 2008; Carpenter, 2002), regulatory delay imposes high opportunity costs for investment, and research and development (R&D) time (DiMasi et al., 2010; Dimitri, 2010; Vernon et al., 2009; DiMasi, 2002). Nonetheless we argue that:

> **Proposition 5:** The actual cost of regulatory reviews rests in the trade-off between providing quick access to products and safeguarding public health and safety.

Furthermore, prolonged reviews may trap innovating firms in a state of uncertainty, thereby limiting the opportunity to obtain time-based advantages and to forecast returns on their investments (Garber et al., 2014; Hirai et al., 2010). It is needless to say that developing NPI requires a huge financial outlay, and innovating firms often resort to venture capital institutions and financial investors to fund the transformation of the innovations from prototype to commercialised product (Burger-Helmchen et al., 2020; Lerner and Nanda, 2020). The concern here is that these investors place high value on the ability to mitigate losses and predict returns on their investments. Prolonged review process therefore fuels the perception of risk and uncertainty and the likelihood of market failure for the 'non-tested' product (Roca and O'Sullivan, 2020; Prieger, 2007). As a result, investor confidence may be distorted thereby leading to the innovating firm's inability to secure investment for subsequent NPI development (Roca and O'Sullivan, 2020; Hoerr, 2011). In a hypothetical illustration to show the impact of regulatory delays on investment, Hoerr (2011) revealed that the longer the review time the more the Internal Rate of Return (IRR) and Net Present Value (NPV) of the innovating firms' investments continue to plummet. As a result, regulatory uncertainty demotivates the innovator's NPI development initiatives. The salient point here is that revenues that could be accrued from commercialising innovation are delayed, yet the costs of resources used in developing the product continue to accumulate. Thus, although regulatory agencies may adopt delay mechanism to accumulate enough data to be certain about the safety and quality of products on the market, they end up exerting extra financial burden on

innovating firms, who may also have incurred huge costs in developing their products and providing the data for regulatory evaluations (DiMasi and Faden, 2009). Overall, we contend that:

> **Proposition 6**: Regulatory review process influence investor confidence and the direction of financial investment as product that are (not) granted authorisation to commercialise become (less) more attractive to investors.

Routines as regulatory concern

The decision-making rules employed by regulatory agencies in the product review process constitutes the basic operational patterns defining the technical or scientific construct within which NPIs are evaluated. As such, the persistent feature of the regulatory review framework, to which the ultimate objective is to approve or restrict NPIs from the market, includes the specific actions, activities, and interactions that the product evaluators enact in the review process. In this regard, we turn attention to the concept of 'routines' and its 'ostensive' and 'performative' aspects to provide some insights into how routines may become a concern in regulatory review processes (Pentland and Feldman, 2005). This is important because these aspects of routines reserve the most important elements that underpin and facilitate the continuous adaptation of the persistent pattern of the new product evaluation processes (Dionysiou et al., 2021). By ostensive routines, we mean the patterns of evaluation which serve as a frame of reference for specific actions or activities executed by reviewers in the NPI review process (Pentland and Feldman, 2005; Becker, 2004). Drawing on this definition, we argue that the regulatory review process, on the one hand, constitutes a standard evaluation script which formally shapes our perception of what the review process entails (Pentland and Feldman, 2005). In other words, this aspect of the regulatory evaluation process provides a generalised representation of what the review process entails. The scientific evidence generated during the various phases of the review process forms the substrate upon which this ostensive strand of regulatory evaluation routines is developed (Sherman et al., 2017). Thus, on the other hand, there are specific actions and practices that define and sustain the ostensive aspect of the NPI evaluation routines (Feldman, 2003; Garud and Rappa, 1994). In this regard, we perceive the review process as constituting concrete actions, instruments and technical processes

employed by reviewers to generate facts for evaluating the NPI and to support a market authorisation decision thereof. From these routine practices, reviewers are able to develop and adjust their evaluation rationale by nurturing "*metistic knowledge*; the acquired practical skills and intelligence, and 'ways of knowing' in responding to changes" (Sarpong et al., 2018, p. 586).

However, Polidoro (2020) argued that as regulators rely on this tacit knowledge acquired from previous reviews to assess NPIs innovations, they tend to include additional issues that are not necessarily applicable to the product under review, thereby creating evaluation incongruities. Thus, the cognitive underpinnings of evaluation routines constitute the fundamental antecedent of delay in regulatory review processes. This cognitive effect occurs because, as reviewers capture the underlying technology on which the prevailing innovations are developed, the review process is rendered routinely and, as a result, successive innovations that are built on similar technologies experience what Carpenter (2002, p. 494) would call the "order-of-entry effects". Carpenter (2002) articulated this order-of-entry phenomenon in a context where the importance and speed with which reviewers evaluate NPI becomes relative to the perceived value that previously approved products may have offered. However, this expression may also serve conceptual vocabulary to enunciating incongruities in review time and regulatory decision between radically new products and incremental innovations (Foucart and Li, 2021; Ellwood et al., 2017; Manders et al., 2016). The analysis here is that as reviewers deepen their knowledgebase of existing technologies over time, there is a likelihood that the initial set of applications will experience shorter review times, as issues that do not constitute the scientific testing rules, such as value addition (Carpenter, 2002), may not be flagged in the evaluation process. However, such non-scientific factors may become consequential in the subsequent reviews. Furthermore, the regulator is more likely to be delay or restrict incremental innovations as they are confronted with the challenge of filtering out from an ever-increasing evaluation criterion. Polidoro (2020) empirically explained that contrary to the innovation firm whose operational routines leads to an exclusion effect, routines have an inclusion effect on regulatory agencies. Therefore, evaluation framework may include additional parameters that may become restrictive to subsequent innovations. Thus:

Proposition 7: The continuous evaluation of NPI cedes inclusion of non-scientific factors that influence the decision to approve or restrict a product from commercialisation.

Yet perhaps the sharpest analysis lies elsewhere. Though routines may underpin delays, it would be inherently partial, as far as routine dynamics and adaptation is concerned, to conceive the enrichment of regulator's understanding of technologies underlying NPIs, which is achieved through evaluation routines, entirely as an antecedent of regulatory delay or as a restrictive measure. Our starting point for providing an intimate understanding of this cognitive effects of routines is by drawing on the assertion that an epistemic interpretation, like a river, flows in both directions (Van de Ven, 1989). Thus, we argue that similar to innovating firms whose technological adaptation is facilitated by the accumulation of knowledge from operational routines (Winter, 2003; Nelson and Winter, 1982), regulatory agencies also rely on evaluation routines to streamline the review process. The cognitive efficiency developed through the repetitive evaluation of products complements the regulatory agencies' effort to bridging the persistent knowledge gap between reviewers and innovators. In turn, the regulatory review framework adapts to the complexities in emerging technologies and responds to the social and institutional environment within which NPIs are developed (Rosenblatt et al., 2016; Gajendran et al., 2014; Ishibashi et al., 2012; Carpenter, 2004). By harnessing the accumulated knowledge from previous reviews, reviewers can identify the subtle technological difference in the current set of innovations under review and previous products. This then enables the product reviewer to sift through the numerous and usually conflicting details about the existing technologies in order to identify the appropriate evaluation criteria for a focal innovation under review. In the FDA's strategic efforts to leverage 'real-world data' (RWD) in order to improve regulatory decisions and post-market surveillance, for example, observing multiple routine clinical practices, and the development of meaningful review patterns was deemed fundamental to achieving efficient review process (FDA, 2018). As such, routines are the important conceptual building blocks that facilitate the adaptation of the cognitive capacity of regulatory agencies to adjust and shape the scientific constructs within which

NPIs are evaluated to meet changing conditions in the innovation landscape (Polidoro, 2020; Gossart, 2005; Feldman, 2000). Therefore:

> **Proposition 8:** Regulatory evaluation routines adapt to technological change by prioritising *metistic knowledge* required to understand the complexities of new technologies underpinning NPIs.

Discussions

This paper began with the premise that the logics of regulatory decisions is derived from the scientific constructs within which new products are evaluated. However, we argued that there are other concerns which influence the regulator's decision to grant or refuse market authorisation for an NPI. In our effort to provide a holistic view on the constitutive role of these concerns in the scientific evaluation process, we developed a conceptual framework and generated propositions which help to unravel how these concerns mutually shape and inform regulatory decisions. In this vein, we argued that speedy reviews remain one of the core concerns of regulatory agencies, as efforts are repeatedly made to provide quick access to products that have the potential to improve the welfare of society. However, we maintained that this objective to expedite the review process could not be at the expense of the regulator's duty to safeguard public health and safety. In this regard, product reviewers expend considerable time and effort to accumulate sufficient data to eliminate uncertainties about product quality and safety (Carpenter, 2004; Olson, 2008). Again, we emphasised that the search for compelling data and in-depth understanding of technology underlying NPIs to improve the quality of reviews may also lead to delays, which in turn imposes considerable cost on innovators and consumers (Carpenter, 2004; Grabowski and Wang, 2008). Consequently, consumers may be denied access to life-saving products while innovating firms may also fail to capture early entrant advantage thereby reducing the incentive to innovate (Prieger, 2008; Carpenter, 2002). On this basis, we argued that in complementing efforts to reduce the cost of regulatory reviews, there is a need to provide solutions to the learning problems and information gaps that underpin regulatory delays. Furthermore, we argued that although the cognitive effects of routines may lead to the inclusion of evaluation criteria which may be inappropriate to the

NPI under review and hence precipitate regulatory delays, the patterns of influence run in both directions. Thus, the routines also have a cognitive effect on product reviewers through the development of important skills and knowledge needed to reconfigure evaluation framework in order to address the rapidly changing NPI landscape.

Overall, this paper presents some compelling arguments offering an important contribution to the literature on regulatory reviews and innovation management studies. First, by complementing the extant emphasis in the literature on the influence of regulatory decisions in defining consumers' evaluation of products on the market (Polidoro, 2020; Rindova et al., 2005; Nelson and Winter, 1982), we provide much-needed clarity on how specific concerns in the regulatory review process play a significant role in articulating the value of NPI to consumers. Thus, although the regulatory agencies do not engage in the market-based exchange with innovating firms, their influence on the consumers' choice of products makes apparent the regulators' power to control the flow of current innovations (Zhu et al., 2017). In addition, we offer a better appreciation of the innovator/reviewer nexus and propose that innovating firms must consider regulatory agencies an integral part of the NPI development strategy, because they wield the power to select out products from transitioning from laboratory to market, and thus shape the trajectory of future innovations. Second, by arguing that the cognitive effects of routines are in fact two different elements of a single phenomenon, this paper underlines the cognitive benefits to regulators when mobilising and reorganising scientific principles underpinning the evaluation framework, in order to adapt to changes in the technologies underpinning NPI. We maintain that regulatory experience forms the basis for product reviewers' ability to finetune their cognitive capacity to activate a dynamic evaluation framework (Teece, 2012; Mina et al., 2008). Thus, we assert that the best way for regulatory agencies to develop and sustain sensitivity to changes in the innovation landscape is to deliberately encode into their formally defined review process the "intervention tools" and tacit knowledge that are initiated and acquired through everyday adaptive practices of product reviewers (Lemon and Sahota, 2004; Gourlay, 2006).

Direction for future research

There are some interesting aspects of the discussions which remain outside our focus of attention and may provide interesting directions for future research which could initiate new scholarly conversations and guide researchers to further extend our understanding of the regulatory review of NPIs. First, we argue that the spectrum of product uses defined by consumers creates disparity between the innovating firms' intended use and the actual market use of an NPI. This is because products that are commercialised on the market hybridise under the conditions and preferences of the selection environment, thereby extending the scope of the product to include unanticipated segments of the market (Cattani, 2006). However, innovating firms often fail to capture diversity in the demographics of consumers who determine this unintended variation in product usage. This phenomenon underlines the apparent surge in post-market failure and withdrawals (Carpenter et al., 2012; Van der Panne et al., 2003) as products become inefficient under these unanticipated conditions. In this regard, we argue that regulatory agencies assume prime importance in booting innovating firms to incorporate market diversity into their NPI design and development. Re-emphasising the power of regulatory agencies to influence the trajectory of future innovations, we argue that the regulator could serve as mediator between innovators and the market by setting standards and evaluation criteria that would ensure that innovating firms infuse sensitivity to market diversity in the design and development of NPIs. This we surmise will also help innovating firms to extend their NPI development initiatives towards the frontiers of technological pre-adaptation and optimise widespread and melange use of products (Shluzas and Leifer, 2014; Cattani, 2006). In this regard, future research should provide ways by which regulatory agencies could broaden the review framework and evaluation parameters to include considerations for diversity in product use.

Second, to the extent that our arguments in this paper hold water we go far enough to emphasise that the power of the regulator in shaping current innovation and the trajectory of future ones could also be influenced by several social, political, and cognitive factors. However, while the existing literature has extensively unpacked the phase-gate review process and the scientific testing

rules that determine approval of product commercialisation, this paper, including the existing literature, has paid little attention to the socio-cognitive aspects of the review process (Garud and Rappa, 1994). We therefore advocate for future research to open the black box of regulatory decisions to identify the specific mechanism through which socio-cognitive constructs emerge and fall out of use in the regulatory review of NPI process.

Third, we argue that the focus of regulatory agencies is drawn in very narrow terms to protect consumers against unsafe or ineffective products with minimal efforts to incentivise continued innovation. As a result, when influencing regulatory agencies to expedite and grant market authorisation for their products, innovating firms often resort to the use of media and consumer advocate groups, coercive pressures, and lobbying (Carpenter and Moss, 2013; Rindova et al., 2005; Carpenter, 2004). There are several notable instances where regulatory agencies, succumbing to media and consumer pressures, authorised the commercialisation of products without adequate scientific justifications (see, for example, Keidan, 2007). Thus, considering lingering concerns about the tendency of regulatory agencies to back the commercial interests of the industry over public interest, we advocate that future research should initiate thorough examination of the strategies employed by innovating firms in establishing and maintaining their influence on the review process, and to suggest ways by which regulatory capture could be prevented (Dal Bó, 2006).

Fourth, although we maintain that routines remain the backbone of organisational knowledge, which help to develop and initiate change and adaptation in regulatory review frameworks, we do not present an empirical account of the mechanisms through which this adaptation process comes into fruition. Against the backdrop of many recent empirical works on routines, which point to the tacit co-ordination of practices as a source of organisational adaptation (Rerup and Feldman, 2011; Gavetti and Levinthal, 2000), we draw attention to the performative aspect of routines (Feldman, 2000; Feldman and Pentland, 2003), as such insights could provide the foundation for building an informed account of the mechanism through which adaption of the regulatory review framework unfolds. Specifically, we suggest that future scholars should focus on the everyday adaptive practices of product reviewers

as they go boldly forward into the empirical wilds, in order to provide an account of how the interaction between "articulable" and "inarticulable" knowledge (Gourlay, 2006) of product reviewers could inform change and adaptation of regulatory review process.

Limitations

Despite the several contributions and rich insights for future research we offer in this paper, there are some major shortcomings that must be mentioned. To begin with, we acknowledge that the empirical foundations of our arguments and propositions are sourced from secondary data that were not collected to serve as a basis for our propositions. Furthermore, the mainstream research on regulatory reviews, which cumulatively informed our arguments, were empirically skewed to the pharmaceutical drug industry. More so, the contributions of the literature used were developed within stable and well-developed institutional settings; a challenge which often lies in the common place of the scholarly works (Adomako et al., 2021; Danquah and Amankwah-Amoah, 2017). Therefore, we concede that this conceptual endeavour may not fully represent the new product regulatory review landscape and that the relevance and generalisation of our propositions might not apply in other contexts. As such, although our propositions are not derived empirically, and therefore lack some robustness, we hope that our work has the merit for laying the necessary conceptual foundations for future empirical work to expand the discourse on regulatory reviews.

Conclusion

In closing, we note that regulatory review has come to dominate discourse on NPI among innovation scholars, policy makers and practitioners. However, we argued that a rigorous debate on regulatory reviews can only be fertile if there is clarity on how (non)scientific logics combine to influence the regulatory review process, and how this entanglement in turn influences the flow of NPIs and their success on the market. In contributing to the discourse, we draw on burgeoning scholarly contributions on regulatory reviews to suggest that regulatory decisions are not only based on the scientific evidence generated in the evaluation process, rather there are other factors that cumulatively influence the

regulators' decision to grant market authorisation to an NPI. We articulated eight propositions which help to illuminate understanding of these underlying factors and their implications on NPI. The paper thus contributes to the literature by emphasising on the centrality of the regulatory agencies in directing and shaping both current and future innovations. In addition, we have strengthened arguments for the significance of routines in the regulatory review process. Specifically, we highlighted on the cognitive effects of routines as having an inclusion effect on the review process, thereby causing flaws and delays in regulatory decisions. Nonetheless, we also advocate that if routines provide a context of learning that enhance product reviewers' understanding of the technology underpinning these NPIs in order to eliminate incongruities in the review process, then it may not be wise to ignore the cognitive efficiency that are derived from the evaluation routines.

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Table 1: Thematic classification of literature sample

Literature	Speed and delay	Routines	Cost and uncertainty	Safety and efficacy
1. Abraham (2002)				x
2. Alleman and Rappoport (2002)			x	
3. Arora and Tosti (2017)				x
4. Berndt et al (2005)	x			x
5. Breckenridge et al. (2011)				x
6. Carpenter (2002)	x	x	x	
7. Carpenter et al (2003)	x			
8. Carpenter (2004)	x			x
9. Carpenter (2008)	x			x
10. Carpenter et al. (2012)	x			
11. Chorniy (2020)			x	x
12. DiMasi et al. (1991)			x	
13. DiMasi and Manocchia (1997)	x			
14. DiMasi (2002)				x
15. DiMasi et al (2003)			x	
16. DiMasi and Faden (2009)	x			
17. Dimitri (2010)			x	
18. Downer (2010)				x
19. Downer (2011)				x
20. Downing et al. (2012)	x			
21. Downing and Ross (2017)	x			
22. Dranove and Meltzer (1994)	x		x	
23. Finkel (1980)	x			
24. Fleming (2015)			x	
25. Friedman et al (1999)	x			x
26. Gans and Ridley (2013)	x			x
27. Garber et al. (2014)			x	
28. Gieringer (1985)			x	x
29. Grabowski (1978)	x			
30. Grabowski and Wang (2008)				x
31. Haines (2017)				x
32. Hirai et al. (2010)			x	
33. Hoerr (2011)			x	
34. Ichimaru et al. (2010)	x			
35. Ishibashi et al. (2012)	x	x		
36. Jones (2015)			x	
37. Kaitin et al. (1991)	x			
38. Kaitin (1994)	x			

39. Kesselheim et al. (2015)	x			

Table 1 continued

Literature	Speed and delay	Routines	Cost and uncertainty	Safety and efficacy
40. Kessler and Chakrabarti (1996)	x			
41. Klonoff (2020)		x		
42. Kuzma, and Besley (2008)	x			x
43. McNamee et al. (2017)	x			
44. Olson (1995)				x
45. Olson (1997)	x			
46. Olson (2000)	x			
47. Olson (2004)	x			
48. Olson (2008)				x
49. Ono, et al. (2005)	x			x
50. Polidoro (2020)		x		
51. Prieger (2002)	x			
52. Prieger (2007)	x			
53. Prieger (2008)	x		x	
54. Ranchordás (2015)	x		x	
55. Regnstrom et al. (2010)	x			
56. Reichert et al. (2001)	x			
57. Ridley et al. (2006)	x			
58. Roca and O'Sullivan (2020)			x	
59. Rosenblatt et al. (2016)	x		x	
60. Sherman et al. (2017)				x
61. Thomas (1990)			x	
62. Tyner and Sadrieh (2011)			x	x
63. Vernon et al. (2009)			x	
64. Vogel (19900	x			x
65. Wrubel et al. (1997)	x	x	x	

Figure 1: NPI commercialisation and the regulatory review process

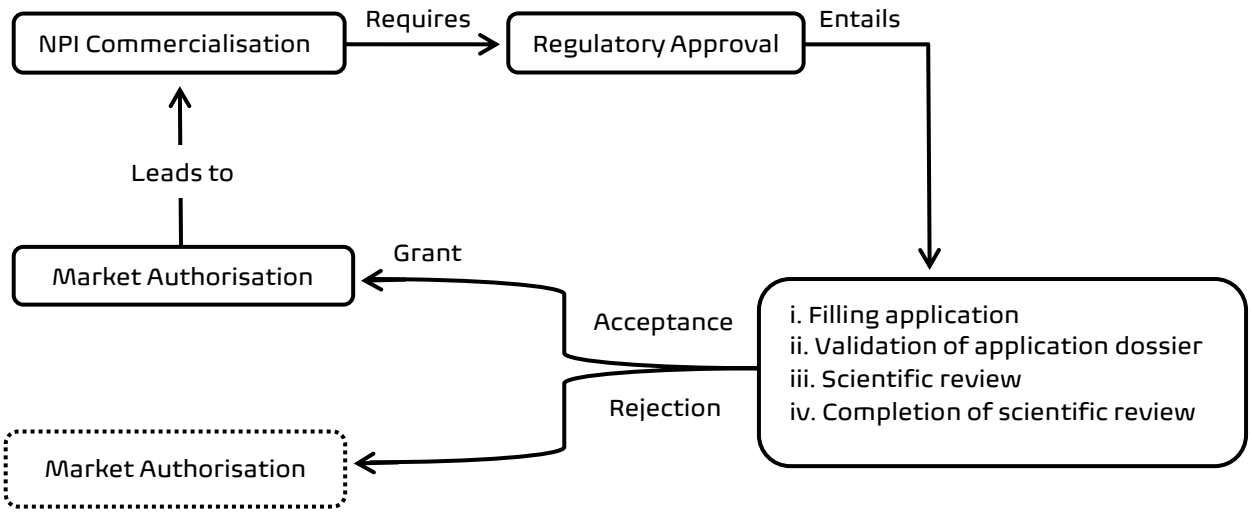

Figure 2: Conceptual model of regulatory review concerns