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Regulating in developing countries: Multiple roles for medical research and products regulation in Argentina and India

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ABSTRACT

This paper engages with the complex relationship between innovation and human health and the role of regulation in bringing the two together, and, in doing so, facilitating inclusive innovation in emerging economies. After outlining the contested role of regulation, we provide two case studies: regenerative medicine regulation in Argentina, and medical devices regulation in India. While these empirically-based case studies examine different scientific sectors in different jurisdictions and therefore have different contextual foundations, they demonstrate the important link between regulatory policies and the successful promotion of innovation. Through them we challenge the oft-repeated complaint that regulation stifles innovation, demonstrating that both a lack of regulation (Argentina) and poorly conceived regulation (India) are equally damaging to innovation, to actor wellbeing, and, ultimately, to human health. We argue that devising new forms of regulation can facilitate increased innovation and thus improved technological (and economic) competitiveness (ie: social/regulatory innovation can lead to improved technological/scientific innovation).

1. Introduction

A range of sectors, activities, and technologies rely on the biosciences, which are increasingly important for translating technical knowledge into useful products, including 'bioproducts' (i.e., products that interact with the biological and which might be administered within the clinical or consumer context). The biosciences and their resultant biotechnologies are integral to the 'bioeconomy', which, though somewhat amorphous, describes the commercial value of, and activities around, biological knowledge and bioproducts, and it is tangled up with the concept of 'innovation'. Sometimes defined as 'the successful application of new idea to use' [34], innovation is the lode-stone of the 'creative destruction' claimed by Refs. [56] [57]; as necessary for economic development.[1] Successful innovation requires appropriate linkages between diverse (and often networked) actors, effective nodes for consideration of the myriad social concerns and technical hurdles, and space to forge unique or alternative practices and processes that are necessary to transform new ideas into safe and effective products [30]. Ref. [22] Governments seek to encourage these phenomena through industrial policies, infrastructure investment, taxation, and regulation.[2]

This paper focuses on the last strategy, regulation, and more particularly regulation in the health technologies setting. While regulation is often not the *main* driver of innovation or healthcare system evolution [67], it can have profound impacts on stakeholder ambitions and activities, and therefore on innovation, on institutional formation, and on knowledge-deployment within healthcare systems. It can influence (and sometimes determine) the types of

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[1] Innovation can be 'path-breaking' or 'path-following'. The former involves changes deemed to be radical or disruptive, whereas the latter, which is more common, relies on small or incremental developments in products or processes within a firm, sector, region, or globally. Transistors and integrated circuits are examples of innovations which caused creative destruction and shifted how actors provide products and offer services.

[2] The impact of government investment and regulation can be observed in the case of the pharmaceuticals industries. In 1880, Germany and Switzerland were at the forefront of drug development and manufacturing. The outbreak of World War II, however, prompted the US to foster massive chemical analysis and commercial production techniques (Henderson et al., 2007). The resultant system significantly improved productivity, and it provided the platform for the US to leapfrog European pharmaceutical companies.

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enterprises that succeed, the types of knowledge that get privileged, and the types of structures that evolve, and so impact on the dynamism of whole disciplines or sectors [62]. Indeed, regulation has been described as a powerful determinant of what we even consider to be 'innovative' [14]. In short, regulation can be an important feature of both the innovation and the healthcare landscapes – which are increasingly overlapping – and of the broader governance processes and structures by which these landscapes are managed [40,63].

In this paper, we are concerned with regulatory vacuums and the subsequent production of regulation in middle-income countries (or emerging jurisdictions) over which there has been limited attention, namely Argentina and India. The former was the subject of an ESRC-funded project called 'Governing Emerging Technologies: Stem Cell Research and Social Values in Argentina' (GET),[3] which gathered qualitative data around key issues of 'regenerative medicine' research governance in Argentina, particularly the role of regulation in facilitating research and the values that should underlie that regulation.[4] The latter was the subject of an Innogen-hosted project called the 'Medical Device Project' (MDP),[5] which investigated key factors hampering development in India's medical device industry (MDI), exploring in particular the role of regulation in the effective diffusion of technology.[6] In short, both projects focussed on fields which are driven by innovation and which are dramatically realigning healthcare and industry practices not only in the subject jurisdictions but around the world. While they were not designed or conducted as a 'pair', they are appropriately considered together because both were informed by the broad relationship between innovation and governance, both reflect a desire to better understand the formation, design, and impact of regulation, and both investigate stakeholder activities and concerns around health-related innovation through empirical research within that emerging jurisdiction.

In the following pages, we introduce the projects that underlie the case-studies, first describing their objectives and methodologies, and then summarising the backgrounds which informed them. We then offer our findings, structuring the discussion around some key issues, namely current regulatory shortcomings and consequences, regulatory objectives or ambitions, and identification of standards. We conclude that regulation can be a boon rather than a burden for a host of reasons only peripherally relevant to risk (which is the most overwhelmingly common driver of regulation). The case-studies also support the conclusion that these jurisdictions (and other similarly situated jurisdictions confronting challenges quite different from those in developed countries) should make every effort to avoid recreating the 'should we/shouldn't we' debate about regulation. Favouring collaborative regulatory design over this dead-end debate could open opportunities to explore new and smarter forms of regulation which might better generate improved bioscience innovations and medical interventions. Before we turn to the case-studies, however, we articulate our concept of regulation, and the nature of the debates that have characterised its evolution.

2. Regulation

The concept of 'regulation' is not uncontested, and the range of instruments and actions caught by the term can expand or shrink depending on the specific definition adopted. We view regulation as a process involving the sustained attempt to control, order or influence the behaviour of actors so as to produce identified outcomes. These outcomes *should* be closely tied (or rationally connected) to the means supported by the regulation for generating influence. While it is possible that a single actor could define all of the key objectives and all of the necessary influence-generating roles and powers to pursue them, such will be extremely rare; many fields, including the technologies innovation and healthcare fields, have very diffuse or 'decentred' operational environments; environments that exhibit characteristics that can frustrate the smooth transformation of policy intent to lived reality, namely complexity, fragmentation, and interdependence [10,64].

With respect to complexity, social problems are caused by many interacting factors, not all of which may be known, the nature and relevance of which may shift over time, and the interaction between which will be imperfectly understood. Additionally, interactions between relevant actors and networks are complex and dynamic because of diverse and shifting interests, objectives, powers, and norms; many actors relevant to a problem will develop autonomously and their behaviour will not remain constant, making interactions hard to predict and hard to manage [10]. Moreover, new stimulants (including the introduction of regulatory instruments) will produce behavioural changes, some unintended, that will be uneven across different actors, thereby adding to the fragmentary nature of the environment.

Second, both knowledge and power/control are fragmented. Knowledge fragmentation is more than just information asymmetry, although that persists. Rather, it is a recognition that complex and dynamic problems require more knowledge than any one body can have, and no entity has either the breadth of vision necessary to employ all relevant instruments to their maximum effect, or the power necessary to wield them all even if they had the sufficiently broad perspective [10]. Power is also fragmented or dispersed, and regulation occurs in many locations and fora, a natural consequence of regulation relying variously on international treaties, agreements and declarations, national legislation and derivative statutory instruments, industry and professional guidelines or codes, and the evolving norms of established and emerging actor networks. The courts are also important regulatory institutions, with the ability to shape sectors; the US Supreme Court's decision in *Diamond v Chakrabarty*, for example, has been credited with a significant role in the rise of the biotechnology industry.[7]

Interdependence describes the reality that, despite some (though differing) levels of autonomy, actors – both public and private – are interdependent [11]. And these actor relationships, which are often symbiotic, are not always bounded by jurisdiction.

[3] See http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/.

[4] The term 'regenerative medicine' refers to that interdisciplinary 'field' of research and clinical applications focused on the repair, replacement, or regeneration of cells, tissues, or organs to restore function caused by disease, defect, injury, or ageing. It relies on multiple converging (and emerging) technologies to move healthcare options beyond traditional therapies, and specifically into approaches that rely on or support the body's own healing capacity. Component technologies include gene therapy, stem cell therapy, and tissue engineering [17].

[5] Seehttp://www.innogen.ac.uk/people/Dinar%20Kale.

[6] The term 'medical devices' captures both simple and highly sophisticated equipment (e.g., everything from tongue depressors, medical gloves and bandages, to surgical lasers, pacemakers, dialysis machines and heart valves) [66]. In contrast to 'medicinal products', whose primary mode of action is metabolic, immunological, or pharmacological, 'medical devices' are instruments, implants, or machines intended to be used, alone or in combination, for one or more specific purposes such as diagnosis, prevention, monitoring, treatment, or alleviation of disease [58].

[7] That case involved a patent claim on a genetically modified, oil-eating bacterium. The US Patents and Trademarks Office (USPTO) rejected the claim on the basis that subject matter (a living organism) was a discovery, not an invention. The Court reversed that ruling and granted the patent, thereby establishing the practice of making very broad patent claims which positively encouraged investment [43].