

# **New approaches to learning and regulation in medical devices and diagnostics**

**IKD Working Paper Number 90**

**March 2021**

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<http://www.open.ac.uk/ikd/publications/working-papers>

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Our research is further supported by The Open University's strategic research areas, in particular International Development & Inclusive Innovation (IDII-SRA).

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## **Abstract**

This paper offers a first step to analyzing sub-sector variation in the learning of firms, and the types of leads or lag in industrial regulation in the Indian health industry, one of the world's largest suppliers across countries in critical generics, vaccines, and diagnostics. Sub-sector variation in an industry's learning and regulation trajectory has received relatively little attention in economic development literature and has important consequences for the design of the industrial policy. The paper appeals to evolutionary and institutional (E-I) approaches in economics, which have made significant contributions in improving the understanding of how firms learn. Our argument rests on institutional cohesion and the difficulty of transferring complexity of learning in a sub-sector to generic industrial regulations. The paper applies a qualitative heuristic focused on co-evolving institutional domains. Also included are brief composites from interviews with diagnostics firms, as well as analysis of types of learning and regulatory lags. The paper finds that although firms continue to learn and innovate, persistent regulatory challenges to firms are generated by the misapplication of industrial policies to diagnostics and devices intended for pharmaceuticals and vaccines. Our findings suggest future research is needed on value priorities for policy design, use, and regulation of diagnostics and devices in healthcare.

**Keywords:** Technological capabilities, medical devices, diagnostics, industrial policy, regulation, evolution, institutions, development

## **Acknowledgements:**

The support of the Economic and Social Research Council (ESRC) (UK) is gratefully acknowledged. The content of this article is the sole responsibility of the authors and does not necessarily reflect the views of the UK ESRC. The authors also acknowledge the support of the National Centre for Biological Sciences-Tata Institute of Fundamental Research (NCBS-TIFR) for their hosting of part of the Innovation for Cancer Care in Africa (ICCA) project. (Grant reference ES/S000658/1). The authors would like to sincerely thank the IKD editor Frangton Chiyemura and anonymous reviewers for valuable comments and are especially grateful for the editorial assistance of ICCA Fellow, Pritika Rao. The authors would also like to acknowledge Prerna Seth and Charis Idicheria for early research assistance in this paper.

## **1.0 How firms learn in economic development: Regulation design in industrial policy**

Economic development scholarship has placed a heavy premium on institutional gains, and better ways of doing things, arising from private and public firms' efforts in building their technological capabilities. This paper contributes a conceptual framework and preliminary novel methodology to address regulatory gaps in industrial policy using India's health industry, one of the world's largest and perhaps most diverse. In the process, the paper has some observations on the practical use of insights from evolutionary, institutional approaches to the study of how and why the learning in firms matters for economic development. Our argument rests on institutional cohesion and the difficulty of the transfer of complexity of learning in a sub-sector to rules of industrial organization and industrial policy. While evolutionary scholars may be broadly agreed that institutional change occurs and selection pressures can be exerted by regulatory design in the use of industrial policy, they may differ on how theory and methods are conceptually or methodologically connected to explain the relationship between regulation and the learning by firms. Any improvement in methods will thus require more attention to how specific learning, regulatory roadblocks and the complex paths emerging from industrial policies are currently designed.

A major view of economic development is as a dynamic evolution explained through theories of institutional change based on the learning of firms. Yet, the microeconomics methods that exist have largely been derived from a mixed theoretical pool of assumptions about search and learning within firms with a hazy regulatory design backdrop. Yet, when firms in healthcare industries learn and develop capabilities across time, they do so shaped by those norms, guidelines, industry rules, governmental regulations that influence the direction and degree of building technological capabilities. For firms that successfully navigate this wider institutional environment, economic development benefits follow. But within a single industry, there may be wide differences in regulation design and how firms respond, critical to both theory and understanding empirical context, not only because institutional permutations may multiply across sub-sectors, but there may be no singly "correct" way to contrast countries in the sub-sector, generating some challenges for global health approaches which are often disease-specific rather than focused on national industrial customization (Srinivas et al. 2020).

From an evolutionary perspective, institutional change occurs not through single institutions, but through bundles of interacting norms and rules that may go together at any time in history and geography (Amable 2000, Srinivas 2012). Regulatory goals become a pivotal element of industrial policies to shape the multiplicity of rules for pricing, competition, or product variety, for instance. Economic development then emerges as a context-specific transformation of learning as firms navigate these regulatory goals and emerge stronger or at least different, through the sieve of industrial policies.

Our interest is in moving from general discussions of learning in economic development to answering the question about the conditions under which existing regulation shapes firms' learning in industrial sub-sectors such as medical devices and diagnostics. The health industry has many different institutional permutations, which underscore the difficulty of single conceptual explanations (Srinivas 2012). The evolutionary scholarship has largely explained how this process of value-addition or upgrading occurs in firms and specific industries and its impact on economic development. Focused on single industry sectors, this

may be more precisely termed “industry trickle up” since the scholarship is less clear in explaining how gains in some sub-sectors of a single industry benefit other sub-sectors such as pharmaceuticals, vaccines, and medical devices (including diagnostics) or “trickle horizontally”.

Sub-sector variation helps clarify why regulation exists and how it can be better designed. Regulatory design resolution for example can bring health and industrial goals closer together. Prior research demonstrates that adjoining countries in the same sub-sector may show substantial variation in building health industry capabilities even if they are broadly agreed on the goals: in Tanzania and Kenya (Mackintosh et al. 2016), and those with similar institutional legacies of laws and policies, may diverge in one industry (Russo and Banda 2015). The importance of local production capability and technological learning is therefore dependent on the types of learning that firms undertake of export competitors, but also from domestic competitors and often collaborators, or those in adjacent sub-sectors. Thus, vaccines and diagnostics firms in cervical cancer may well be potential ecosystem collaborators offering complementary products and services. However, if competition is considered an essential industrial policy ethos for a country, and early screening of a disease a central health policy goal, then whether or not to require, and how to regulate competition among early screening diagnostics firms is likely to be an essential element of planning and policy, which may generate challenges if not explicitly discussed and resolved. Consequently, the wider economics scholarship built on cross-industry learning has highlighted how countries advance through manufacturing, issues that have served well to analyze economic development, but may be poor explanations for why some sub-sectors in the same industry do much better than others.

Firms learn and change within an – usually national – institutional context where changes may be slow in why or how regulation is done, and these firms may face unique international regulatory features related to quality, safety, efficacy or costs. Firms may sometimes learn irrespective of these national and international regulations, but they may struggle to convert such learning into production and innovation gains. Health industry exporters are also regulated by importer country regulations. Some evolutionary-institutional approaches have developed systemically bringing health and industrial systems together and determining their mutual institutional overlaps and divergences using a co-evolutionary, combinatorial approach (Srinivas 2012); others rest on uncertainties and evolutionary features of system demand (Hodgson 1988); some underscore local production capabilities in specific geographies (Mackintosh 2016); interventions to define market structure such as intellectual property rights or price regulations (Chaudhuri 2005); others on public planning and administrative processes to encourage problem-solving (Banda and Russo 2016); generics upgrading and market dynamics (Kale, 2018); or the political economy under which specific stakeholders can improve the health industry’s social mandate (Kale and Wield 2018; Papaioannou et al. 2016). This wide body of scholarship, largely built over the last decade and a half, reveals important country similarities and differences in how industrial capabilities may be converted into health gains.

Firms function and adapt to their institutional context and must develop viable organizational routines to do so (Nelson and Winter 1984); but they must also develop relational firm-level managerial and project execution features (Amsden 1989; Lall 1984). Some will be

transformed by technology and industrial policy (for example see Lall and Pietrobelli 2005), and the specific hurdles of technology transfer and innovation in developing countries (Arocena and Sutz 2000; Srinivas and Sutz 2008; Kaplinsky 2010; Chataway et al. 2014). A particular challenge occurs in domestic planning processes of identifying and adapting these gains in learning to significant unmet needs and demand (Srinivas 2018). While industry associations can mediate some of this identification and matching of industrial capabilities to domestic demand, national experiences show differences in how the relational process emerges and takes root (Papaioannou et al. 2016). For example, the Indian government was increasingly guided by industry associations on industrial protection policies, negotiation of flexibilities under TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) and development of biosimilar regulations in the pharmaceutical sectors. However, the pharmaceutical industries in some developing countries suffered from the lack of industry associations and their representation in government policymaking, severely affecting the development of the local firms. Similarly, other non-state actors can play a critical role in acting as centres for investment, technology transfer, and training, as more diffuse 'knowledge intermediaries' and in building programmatic ties with the state in order to represent underserved populations. This is also evident in the significant role played by a network of public research laboratories in the form of the Council for Scientific and Industrial Research (CSIR) laboratories supplying trained scientists and also emerging as one of the sources of industrial entrepreneurs a decade later.

The paper is, therefore structured as follows. Section 2 discusses the regulatory design and institutional theory. In Section 3, we turn next to the emerging production successes occurring in India, already seen as "supplier to the world", and whose gains in pharmaceuticals have led to mixed fortunes in medical devices and diagnostics. The methodology, therefore, qualitatively differentiates within-sector variation that tracks the difficulties of translation of learning gains from the highly successful pharmaceuticals sector to vaccines and to medical devices and diagnostics. In the absence of systematic problem-solving efforts, the two challenges converge - of consolidating manufacturing gains and of differentiating institutional design within the "industry" which may be too quickly collapsed together, despite its three very different sub-sectors, each with its specific industrial dynamics and health effects. We conclude with some implications for regulatory policy and the use of specific industrial policy instruments.

## **2.0 Evolutionary-Institutional (E-I) approaches**

### **2.1 Institutional change as a complex, combinatorial process**

To shape the environment of firms in order that health services and outcomes benefit, is of critical importance in the world today. The premise here is that more tightly intertwined industrial and health policy domains rely on improved evolutionary-institutional methods for understanding regulatory design.

Differences in learning across sub-sectors, therefore, matter for regulatory design that may treat the health industry as one institutional story. The seen consequences may be also framed theoretically in terms of evolutionary economics e.g. the selection of technology choice by firms or through policy measures, the selection effects of regulation which reduces the number of firms or their products or services, and the selection effects of specific

industrial policies which may “target” some types of technological capabilities, types of firms, or products. In evolutionary-institutional explanations, technological capabilities are selected by their policy environment. Including some effect from regulatory lag, or catch-up, means that as regulators better understand how firms are changing and what incentives or pressures to use, data may demonstrate if they assist firms to grow and innovate, do nothing to help, or worse, place obstacles in the paths of firms. The various ways of building technological capabilities for example, become a key explanatory requirement to understand development. Until institutional variety can be fully explained, economics struggles to explain what to infer from different pathways to technological capabilities (Srinivas 2020). Therefore, rather than an inevitable progressive system, dynamics may create open-ended sub-systems and unexpected pathways in which policy selection effects can manifest: for example, the combinatorial aspects of co-evolution of distinct institutional domains (Amable 2000). Even among those evolutionary perspectives that recognize the benefits of a neo-Schumpeterian perspective, sub-schools offer diverse value propositions for the goals of learning and the importance of processes and protagonists in building equitable and cohesive versus fragmented systems (Papaioannou and Srinivas 2019).

A dynamic approach to institutions is therefore necessary to capture the evolutionary process of regulation design as well as search and learning in firms. Firms function within a wider institutional environment and their organizational strategies change with this environment, and their routines endogenize the uncertain environment in various ways (Nelson and Winter 1984). At the same time, a dynamic institutional approach requires a combinatorial strategy because institutions change in combination, not one at a time (Amable 2000). For example, specific stakeholders are more evident in some products, sectors and countries. Consequently, while the theories of learning-induced economic development offer robust explanations for institutional change of a certain type, i.e., single-industry/multiple countries, and single-country/multiple industries, they are more hesitant about those that combine two or more institutional domains or those that involve varying degrees of sub-sector differentiation in a single industry. Frameworks of comparative national health industries and their characteristics are analyzed to reveal specific institutional contrasts (Malerba and Nelson 2012; Srinivas 2012; Kale 2019; Mackintosh et al. 2016). Iconic health examples such as the Jaipur Foot prosthetic or the Hib vaccine emerged from NGOs or the state by generating detailed health assessments of needs and demand (Srinivas 2018).

Elsner (2017) for example, points to promising cross-fertilization and useful commonalities between different Evolutionary-Institutional (E-I) methods, which include System Dynamics, (Evolutionary) Game Theory, Simulations, Social Fabric Matrix approach using network analysis and graph theory, and others. Thus E-I approaches are not value-neutral either in methods or in theory (Elsner 2017) because they may include policy design, conflict of means and end, and fundamental issues about technology selection and contingent technology progressiveness (Srinivas 2012). Any improvement in methods will require more attention to how specific learning and regulatory roadblocks and the complex paths emerging from industrial policies as currently designed. The more technological advances occur, the more challenging a domestic political economy becomes, not less, as one might assume (ibid). Therefore, we should expect more sub-sector differentiation to emerge and more regulatory fine-tuning within industrial policy, even while some standardization occurs as countries industrialize.

## **2.2 Sector and sub-sector heuristics: regulation and E-I methods in context**

The case of the Indian health industry (“Supplier to the World”) and 3 sub-sectors – pharmaceuticals, vaccines, and diagnostics, permits closer scrutiny of the underlying economic assumptions of the traditional theory of technological learning and institutional readjustment and intra-industry explanations for variation in the dynamics of industrial and regulation policies. The methodology here differentiates within-sector variation that tracks the difficulties of translation of learning gains from the highly successful pharmaceuticals sector to vaccines and to medical devices and diagnostics. The argument rests on institutional cohesion and the difficulty of transferring complexity of learning in a sub-sector to rules of industrial organization.

This section applies a qualitative heuristic (Srinivas 2012) to demonstrate the different learning pathways of medical device firms. The heuristic offers a qualitative way to trace different evolutionary features of the sub-sectors and their need for better honed regulatory design. Heuristics are methods used across disciplines from mathematics to economics. They are not algorithms, rather are better seen as rules of thumb, shorthand, and guides, and can be used as a thought experiment to offer great power to practical problem-solving and policy considerations. We use the triad systematically using “snapshots” of industrial evolution in one country by drawing on secondary data and the authors’ prior experience in these sub-sectors to look at the challenge of problem-solving as a type of experimental governance in these domains (Srinivas 2020). We find that the methods resolve some forms of regulatory lag that do not track how firms learn or keep up with specific challenges they face in one sub-sector, diagnostics, versus another, generic drugs. Three steps are followed where in Step 1, three sub-sectors are briefly analyzed to differentiate distinct learning paths for firms in broadly similar regulatory environments. In Step 2, we address the case study of the medical devices (devices and diagnostics) sub-sector in more detail. Tables 1, 2 and 3 provide the specific types of technological capabilities being built, the industrial regulation lag, and challenges for firms. Specific Indian medical guidelines and regulations are discussed in terms of their implications for market creation and regulation of diagnostics e.g. affordability and the technical standards and procurement in order to achieve this. Finally, in Step 3 as part of a multi-country project on Innovation in Cancer Care<sup>3</sup>, we provide two interview composites of diagnostic firms and their challenges. These are discussed in brief to point to some of the regulatory issues that firms face and how learning and innovation may emerge and could be strengthened.

## **3.0 Qualitative Heuristics in the Health Industry**

### **3.1 Step I Co-evolving, combinatorial learning paths and regulations**

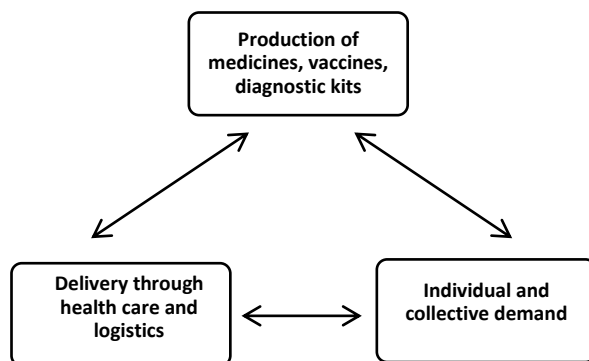
The pharmaceuticals, vaccines, and medical devices industries are critical sub-sectors in healthcare technology industries that play a significant role in diagnosing, treating, and curing diseases. A fundamental concern is understanding the conditions under which industrial and health policy goals can be brought closer together. The methodology employed here uses a qualitative heuristic initially developed for a one-country, one-industry analysis to assess evolutionary snapshots of institutional bundles. The heuristic of the institutional “triad” (Srinivas 2012, 8) breaks the analysis and periodization of the health industry into three distinct institutional domains: production (1), delivery (2) and demand (3).

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<sup>3</sup> <https://www.open.ac.uk/researchprojects/innovation-cancer-care-africa/>



**Figure 1 Institutional triad**



Source: Srinivas (2012, 8).

The real-world implications of the co-evolution of these domains shows interdependency of among production, demand and delivery, across the spheres of industrial policy (1) and health policy (broadly 2 and 3). The triad heuristic provides a shorthand to understand the co-evolving institutional contexts of the health industry, and its specific institutions such as rules, standards, and norms. The “markets” of the health industry can be described through an “institutional triad” of three co-evolving domains of production, demand, and delivery, in which industrial development literature has well described the production elements of manufacturing, testing, prototyping of technological capabilities, but struggles to connect analytically and programmatically to the demand and delivery political economy of health policy.

The measurement of introduction, lead or lag of policies and how firms learn in conjunction or their absence, show that qualitative heuristics can play some conceptual utility for the health industry (Srinivas 2012, 2016, 2019, 2020). “History-friendly” analyses have largely been relegated to simulations of industrialized economies and industry sectors such as semiconductors and pharmaceuticals (e.g. Malerba and Nelson 2012). Unlike simulations, which are sensitive to initial conditions and models of evolution, the qualitative heuristic here is built on the assumption that institutional variety is multidimensional and an ongoing process through which the co-evolution of industrial and health policy occurs. Thus, qualitative analysis features figures of stylized longitudinal product maps, reflecting a concern with how longitudinal industry narrative is presented to refine industrial and regulatory policy design. Thus, from roughly the 1950s to the 2000s, the evolution of India’s health industry with successive capabilities in generic pharmaceuticals, vaccines, and biotechnology capabilities can be captured in a series of national and international “snapshots”. We combine this with secondary qualitative data and corroborate its technical features with authors, with economics, S&T policy, and experience working in the Indian diagnostics industry.

Our methods recognize the following features of note in the heuristic above: “industrial policy” (1) often administered in national ministries of industry and commerce or finance are traditionally concerned with diverse planning elements for industrial dynamism: set-up,

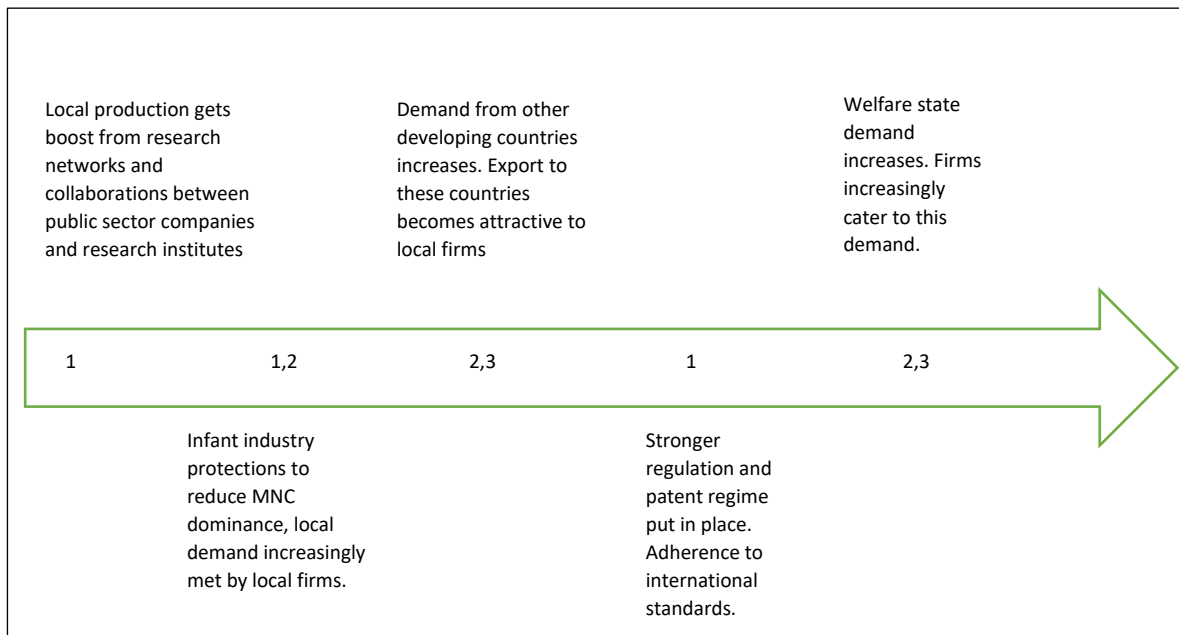
investment, approvals, targets, subsidies or other fiscal instruments, trade tariffs and non-tariff barriers such as technical standards. It also considers compliance with a range of regulatory functions including quality and safety, pricing, labour, and different grades and frequencies of checking that the permitted functions are undertaken to build and maintain a firm or an industry's standing. As can be seen, features of "industrial policy" may substantially overlap with "health policy" (2,3), although the nature of such overlap is institutionally demarcated and enacted in distinct ways. These overlapping goals – but not the process – may include items such as appropriate pricing (e.g. "affordable medicines") or safety (which may include technical standards such as laid out by the relevant Food, Drug, or Chemical regulations in the country and specific to the industry).

The next section lays out prior research findings on the Indian health industry across its three sub-sectors. The health industry is a classic case of considerable industrial policy success over the last several decades, especially in generic pharmaceuticals and vaccines.

### **3.2 Step 2. India's sub-sector dynamics: Pharmaceutical learning and learning from pharmaceuticals**

No industry has more resoundingly contributed to such gains in capabilities in select low and middle-income countries (LMICs) than the health industry, and no country with perhaps more evidence of this than India (Lall 1987; Sahu 1992; Kale and Wield 2018; Srinivas 2012). While the early industrial policy goals for this industry emphasized infant industry protections (Sahu 2014), they were structured to induce a range of industrial capabilities. Specific policy instruments such as canalization – protected imports and procurement of raw ingredients of chemicals, for example – did double duty as regulatory levers to induce a set of long-term capabilities in the national interest (Ibid.). Srinivas (2006, 2016) underscored the challenge of how advances in technological capabilities initially driven by state goals, ironically through considerable public, then private sector success, made policy priorities less obvious and more difficult to regulate. Success in technological capabilities induced more challenges in deploying industrial policy instruments and made the scope of regulation more complex. Problem-framing and solving, relatively clear in a "first market environment" led to considerable success for India's path today; yet for both pharmaceuticals and vaccines, different types of export inducements and search and learning successes in a "second market environment" from early 1970s onward (where significant export capabilities were built), led to contrasting consequences for domestic health regulation (Ibid). Price controls have been a continuous feature of many Indian policies, with mixed effects over classes of problems (Chaudhuri 2019). In particular, '3 Ws' (WHO, WTO and Waxman-Hatch) in a second market environment played significant roles in shaping Indian exports (Srinivas 2004, 2006, 2012). WHO guidelines and procurement strategies in close conjunction with national extended programmes of immunization, led to more precise institutional networks of developing country vaccine manufacturers, and considerable induced technical standards upgrading and rewards from international procurement.

**Figure 2 Snapshots for pharmaceuticals**



Source: Adapted from Srinivas (2012,8) by the authors

In Figure 2, an extrapolation of the heuristic is captured across time in “snapshots”, reveal how generic pharmaceuticals under heavy regulatory oversight and industrial clarity of national goals, advanced by the dominance of 2+3 dominating 1 in the first market environment (FME), while for the second market environment (SME), the growing dominance of technological capabilities in 1 especially through attractive export markets dominated by foreign health, not industrial policy inducements through welfare state buying and institutional procurement. This resulted in the dominance of 1 over institutional norms of 2 and 3 (Ibid). In this explanation, the state is not a passive inducer and responder, or what evolutionary scholars would term a selection environment. Rather the state actively intervenes to different degrees in all three institutional domains in the heuristic, and all three institutional domains are increasingly “industrial” in organization, not merely the realm of production (1). This critical interventional role of the state has been termed by Mazzucato (2018) as entrepreneurial arguing that the state can proactively promote the emerging high growth but high-risk areas by funding the most uncertain phase of the research and even overseeing the commercialization of products or services. This implies that delivery (2) in the triad becomes increasingly technologically driven (e.g. radiology tests, telemedicine, tele-diagnostics, pathology labs using new business models for just-in-time delivery, or other modifications) and thus itself capable of industrial gains. Similarly, consumption/demand (3) especially in growing welfare states, uses technological capabilities to identify people, establish the legitimacy of claims, calculate benefits, and apportion the interface with delivery.

As countries have industrialized, the institutional design of technical upgrading and the building of technological capabilities has increasingly depended on exports. The successes of countries, such as India, in pharmaceutical and vaccines have underscored the importance of manufacturing improvements that were rewarded by export markets. This was not a feature however of every major policy goal. On the contrary, while the successes of the

early years were indisputable, the successful combination of policy inducements and regulatory controls of the infant industry “first market environment” (FME) created their own challenges in turn. As public firms became critical repositories of capabilities even if not always highly efficient, private firms began to grow through a multiplicity of strategies, often by direct migration from public sector firms, but also in joint ventures, technology transfer, and later, from universities and research institutes. While the FME set the stage for remarkable successes for public and private firms alike, a Second Market Environment (SME) defined the export conditionalities and tight standards under which private firms began to grow rapidly (Srinivas 2012, 2016).

### **3.3 Vaccines**

Vaccine markets and their regulations are dissimilar from both pharmaceutical markets and devices. This is because vaccines for communicable disease build on network principles, and those for paediatric effect build on compounding effects of immunity over time. Programmatically, vaccines required depend on effectiveness through crowding in use, and network spread requires low cost or zero cost to the patient. This implies that a range of vaccine characteristics that exemplify the technological capabilities of vaccine suppliers, follow a considerably different economic path from diagnostics or medicines. In vaccines, heavy subsidies are meant to ensure low or zero cost to consumer, and the subsidies and procurement initiatives can and have been effective in health policy (affordability, access, the spread of use, safety) and industrial policy (technological capabilities in R&D, manufacture, technical standards and safety and quality concerns). Related domains of innovation, technology, and science policy have also been integrated into this effort.

Indian industrial and market regulators and health policy experts have largely known how to answer these questions after many years of iterative learning and failures (Srinivas 2006, Madhavi 2003), although clear instances of unclear market rules, heavy-handed state intervention, and problems with pricing have all been witnessed. Madhavi (2003) argues that private vaccine manufacturers have often lobbied for the inclusion of their vaccines into the extended programme of immunization, a questionable practice. Broadly conceived, however, health goals and industrial upgrading occurred alongside the efforts of a wider array of national and international stakeholders.

In particular, the SME began to define the differences in outcomes between sub-sectors of the health industry: pharmaceuticals and vaccines for instance, given the differences between on and off-patent medicines on the one hand, and vaccines on the other, demonstrated the specificity of how international procurement as a demand-side regulatory environment influenced the industrial as well as safety, quality, and affordability outcomes (Srinivas 2006). Vaccines’ quality and safety capabilities grew in a nurturing environment of international manufacturing networks and assured procurement from India’s Extended Programmes of Immunization as well as associated international procurers such as the WHO and United Nations Children’s Fund (UNICEF) (ibid). Generic pharmaceuticals on the other hand, while also depending on both Indian and other international procurers for health programs, advanced with its own private strategies in the SME. By the end of the SME and certainly by the third market environment (TME), India had become the “supplier to the world” but how it did so in generic pharmaceuticals and vaccines was notably different, built over at least three distinct market environments from 1950 to present (Srinivas 2012).

Pharmaceuticals and vaccines from India were thus both successful in supplying the world because in the first and second market environments, industrial policy instruments strategically or unwittingly worked also as standards and quality upgrading regulatory instruments, with price controls as well serving to further the norms of market variety and competition rather than stifling them. For instance, it is evident that in Indian vaccines, demand-side inducements on market variety and size were not utilized to their full potential. More policy pressures could have been exerted to ensure that a range of vaccines became available and that more vaccine firms could have emerged (Srinivas 2006). Yet, because vaccines are regulated as “public goods” and manufactured, procured, and sold differently from generic drugs, they create different norms and expectations about the impact of regulations on buying process, costs to the public, and nature of firms and technologies. It can be argued that as private firms became more cash-rich and experienced export successes, the national controls became less effective, and the differences became more visible between production-inducing instruments of industrial policy and those of regulation and control.

Pharmaceutical manufacturing capabilities and the world-class technological capabilities generated in some late industrializers such as India, have provided a compelling reason to explain not only how the technological cavities were generated and sustained, but also how the institutional design considerations have changed over time. As scholarship has shown, the growing technological learning has required increased experience in coordinating an institutional variety of multiple markets, the difficulty of transferring learning across products and processes, of experimenting with new business models and designing in situ new regulatory frameworks for domestic capabilities with few relevant foreign experiences (Kale 2019). Furthermore, strong supplier countries in pharmaceuticals for example, are able to establish semi-dominant global positions in other health industry sub-sectors such as vaccines or devices. However, the challenge even for the more successful countries such as India or Brazil, has been how to convert the technological capabilities and manufacturing successes into robust institutional gains across sectors and institutional domains beyond production successes. Indeed, as Srinivas (2012) has shown Indian production successes have made the domestic political economy challenges more acute as both firms and the state have struggled to embed the R&D and manufacturing with demand and delivery institutional domains within the country. Diverse market environments provided an explanatory framework for the norms and rules to explain institutional change over time and the difficulty of forcing the convergence of industrial and health policies.

Industry sub-sectors have different dynamics and require overt plans. This is especially necessary for sub-sectors deemed to be in the national interest, where national missions, WTO rules, and business clarity and industry association coordinating could be best exploited. For instance, while in overall telecommunications, Indian policy did well in promoting capabilities in hardware and software, it did somewhat poorly in some sub-sectors such as broadening out fibre optics, materials advances, battery devices, or sustainable extraction for the metals used.

Industrial policies can appear common to sub-sectors, but in fact, as policy bundles can rapidly advance some versus others, even when all sub-sectors are considered important. In pharmaceuticals, India strategically used aggressive bundles of industrial policies –

procurement, intellectual property, fiscal incentives – but the same bundles without differentiation may adversely affect other sub-sectors. In vaccines, for example, procurement design itself requires minute tweaking in order to fine-tune incentives for technological upgrading but has broadly aligned with donors' intent (Srinivas 2006). However, in boosting pharmaceuticals, countries have very unevenly used procurement design to pressure donors to align with domestic priorities (Chataway et al. 2016). Encouragingly, many countries are now achieving a hard-won R&D, prototyping and manufacturing capability in specific aspects of the health industry such as generic pharmaceuticals yet struggle to convert these capabilities into gains in other health industry sub-sectors such as vaccines, or medical devices and diagnostics.

### **3.4 The Medical devices and diagnostics sub-sector**

Medical devices and diagnostics cover screening, diagnosis, and treatment, and may include a range of engineering instruments and medical in vivo and in vitro diagnostics (IVD) such as cardiac stents, bone caps, catheters, metal prosthetics, and x-ray machines. These devices are critical by themselves, such as heart stents, but are also valuable in determining the efficacy of a course of therapy or in conducting pharmaceutical research - making them an increasingly important sub-sector in the health industry. While the health industry is usually analyzed under one umbrella of policies and regulations, urgent questions are being raised about the distinctiveness of devices and diagnostics. There are some key differences that exist among healthcare technology industries relating to the mechanism of action, role of users, nature of regulation and product development process (Table 1). Unlike pharmaceuticals and vaccines, the performance of medical devices depend not only on the device itself but also how it is used, which has implications for setting up a regulatory framework for medical device and diagnostics industry.

The regulatory framework in healthcare technology sectors primarily shares similar objectives: to ensure a level playing field for global trade and access to liberalized markets, to enhance human well-being, and to secure health promotion (Altenstetter 2014). They represent a specific and critical institution as they frame the norms, rules, customs and routines (both formal and written, or, more often, informal and internalized), which govern every aspect of the industry. The regulatory framework influences the structure, function and behaviour of organizations in the industry. However, medical device and diagnostics need a different set of regulations compared to pharma-biotech products as the intended primary mode of action of a medical device on the human body, in contrast to that of medicinal products, is not metabolic, immunological, or pharmacological. As a result, medical devices and diagnostics around the world are classified based on their safety requirements and several criteria are considered to evaluate the potential risk: the degree of invasiveness, duration of contact, affected body system and local versus systemic effects.

The comparative analysis of medical device regulations in advanced countries suggests that the emergence of innovative technologies, a globally operating industry and locally delivered healthcare are key drivers of medical device regulation (Altenstetter 2014). More significantly, this analysis suggests that the strong government-industry linkages and global harmonization agreements are key processes that drive and shape medical device regulations in advanced countries. However, medical devices and diagnostics have several unresolved questions on how to frame and address technological advances, and under what conditions the state can establish clear-cut and credible inducements and regulations for this sub-sector, which is in many respects an industry in its own right.

**Table 1** Differences between medical devices, diagnostics and pharmaceuticals

	<b>Medical devices</b>	<b>In Vitro Diagnostic Medical Devices</b>	<b>Pharmaceuticals</b>
<b>Mechanism of action</b>	In vivo and/or ex vivo use	<i>In vitro</i> use	<i>In vivo</i> use
	Most act through physical interaction with the body or body part.	Tests performed on samples (e.g. blood, tissues, saliva, faeces or urine) taken from the body No direct contact with human body - No need for “clinical trials” with patients => “performance evaluations” of IVDs with samples	Products are administered by mouth, skin, eyes, inhalation, or injection and are biologically active; effective when absorbed into the human body. Often act systemically on the entire body.
<b>Purpose</b>	Diagnostic or therapeutic intended uses	Diagnostic intended use	Therapeutic intended use
<b>Outcome</b>	Outcomes of use often depend directly on skill or experience of user	Outcomes generally not dependent on skill or experience of user	Outcomes generally not dependent on skill or experience of user
<b>Active Components</b>	Generally based on mechanical, electrical, and materials engineering.	IVD components have no therapeutic effect – only used for diagnosis. Key components are those essential for detection of the analyte of interest. Biological core reagents (e.g. antibodies)	Based on pharmacology and chemistry. Now encompassing biotechnology, genetic engineering.
		Performance of tests (e.g. sensitivity, specificity) depends on design of test, geographic variations of the infective agent, populations, and the setting of use	Pharmacologic properties and action of active ingredients are known, based on pre-clinical and clinical studies
		Variable batch sizes for a given reagent, individual batches of the same reagent may use different starting materials.	Standardized batch sizes, manufacturing processes and starting materials.
		Stability varies between products and may vary between batches. Generally stored at 4°-8°C Generally short shelf lives (< 12 months)	Products stable. Generally stored at room temperature Generally long shelf lives
	Many medical devices incorporate and are driven by software	Some IVDMD incorporate and are driven software.	Software is not incorporated.
<b>Product development</b>	Wide variety of products and applications – from thermometers and bandages to pacemakers to x- rays	Products are usually in the form of reagents (solutions, coated microwells, strips). Wide variety of IVDs designed for different indications (e.g. screening, confirmation, monitoring of treatment)	Products are usually in the form of pills, solutions, aerosols, or ointments
	Designed to perform specific functions and approved on the basis of safety and performance	Product development by discovery, evaluation, and approved on basis of performance	Product development by discovery, trial, and approved on basis of safety and efficacy
	Many products developed by doctors or nurses	Products developed in laboratories by chemists and biologists	Products developed in laboratories by chemists and pharmacologists.
<b>Regulation</b>	Most devices cannot be evaluated with randomised clinical trials.		Extensive use of randomised clinical trials to test safety, efficacy and quality of the pharmaceuticals and vaccines

Source: Global Medical Technology Alliance, 2015 and author modifications.

While these guidelines serve as a voluntary set of norms and standards for regulatory agencies and manufacturers, they can be advantageous and can play an important role in reducing the regulatory load and promoting industry compliance. They address issues of effectiveness and safety very thoroughly, and a high degree of congruence exists in the technical standards recommended by the guidelines and the development of International Organisation for Standardisation (ISO) and International Electro Technical Commission (IEC) technical standards. For manufacturers, adherence to these guidelines builds trust and provides access to more markets. However, these WHO guidelines have proved inadequate in the development of regulatory framework for medical devices in developing countries including India.

### **3.5 Evolving Indian medical device guidelines and regulation**

The Indian Ministry of Health and Family Welfare (MoHFW) and the Central Drugs Standard Control Organization (CDSCO) are the main regulatory bodies responsible for overseeing governance of medical devices and diagnostics. The CDSCO exercises regulatory control over the import of drugs, devices, and diagnostics and approves new medical products and clinical trials.

Before 2005, medical devices in India were largely unregulated. Indian medical device manufacturers voluntarily attained certifications from the Bureau of Indian Standards (BIS) but mostly for low-tech instruments. The demand for high-tech instruments was met with an influx of imports following trade liberalization in the 1980s and 1990s, with 70% of the market still remaining import-driven (Kale and Wield 2018). Even with access to new devices, a largely unregulated market, explained in part by the government's "limited understanding of how medical devices work", left consumers unprotected and presented roadblocks for innovation (Kale 2019).

An incident in 2004 at a hospital in Mumbai triggered the debate and development of Indian medical device regulations. The state-run hospital in Mumbai used drug-eluting stents manufactured by a Netherlands-based company despite those stents not having been approved for use in Europe. This resulted in the High Court ordering the government to set standards for the import, manufacture, sale, and distribution of devices. In response, the government amended the Drugs and Cosmetics Act 1940 (D&C Act) and the Drugs and Cosmetics Rules 1945 (Rules) to cover ten specific medical devices. The primary objective of the D&C Act, which is administered and enforced by the Drugs Controller General of India (DCGI) and the Central Drugs Standard Control Organisations (CDSCO), is to promote safe and effective healthcare by regulating the import, export, manufacture, distribution, and sale of drugs, cosmetics, and (now) devices.

This early model for Indian medical device regulation was based on drug regulation (D&C Act) before splitting off from it. The inherent differences between drugs and devices make uncritical application of drug regulatory model for device governance significantly challenging, and in the Indian case, this conflation of medical devices and diagnostics with pharmaceuticals led to severe licensing inconsistencies and delays. It was only in 2009 that the D&C Act was amended to include a discrete—albeit extremely limited—chapter on medical devices.



The largest initiative towards comprehensive regulation for medical devices came from the introduction of Medical Devices Rules, 2017 (MDR). The establishment of the Medical Device Rules, 2017 brought a novel departure in the regulation of medical devices and diagnostics. Whereas a notified list of devices was previously classified as drugs under the D&C Act, based on consultations with the Drugs Technical Advisory Board (DTAB), the revisions contained in the Medical Device Rules, 2017 present a more comprehensive regulatory framework for medical devices of various classifications (see table 2 below). As seen in the table, drugs and devices are a concurrent subject, with both state and central government involvement in licensing and regulation.

**Table 2** Medical devices and diagnostics: Regulatory lags, challenges and impact on triad of institutional domains

Regulation	Challenge	Impact on the triad institutional domains		
		Production	Delivery	Demand
<b>Trade policy</b>	Higher import duty on components rather than final products	More direct import of products than local manufacturing.  In some cases, the import duty on parts added nearly 40 per cent to the cost of manufacturing the device locally.	Medical devices delivery is dominated by traders who acts as distributors to hospitals. These distributors prefer importing the products from overseas rather purchasing locally	Created the key issues of affordability of local users as lack of local production, import cost and distributor profits led to significant increase in the cost.
<b>Drugs and Cosmetic Act</b>	Regulates devices and diagnostics as drugs and vaccines  Shortages of testing facilities	This mismatched regulation led to increase in the cost of production as firms had to create facilities that are not needed.  Lack of testing facilities added major hindrance in supporting local firms.	Some companies struggled to get licenses for products even when they had been on the market for more than two decades severely delaying the delivery of products.	The mismatched regulations didn't prevent entry of spurious and counterfeit medical devices and diagnostics
<b>Drug Price control order (DPCO)</b>	Operational challenges	DPCO reduced incentives for firms to invest in development of the innovative products but discouraged use of new products.	The new prices affected the supply of the certain medical devices as reduction in the profit margins made them unattractive for suppliers.	DPCO led to withdrawal of products from the market affecting the availability of certain types of medical devices.
<b>Procurement rules</b>	Requirements of certain firm size to qualify for tender process	These rules prohibited start-ups and new local businesses from tendering processes	Distributors mainly concerned about profits than innovative local products. These rules reinforced the domination of MNCs on delivery of medical devices	Makes it harder for local users to access appropriate devices

Source: Authors modification based on Kale and Wield, 2019.

The MDR rules, 2017 introduced a risk-based classification system, application of regulatory standards, proper manufacture licensing requirements, shelf life restrictions, quality management system and more focused clinical regulations. These rules also seek to nurture a culture of self-compliance by medical device manufacturers and create a robust ecosystem for all stakeholders, including innovators, manufacturers, providers, consumers, buyers, and regulators. Medical devices have been divided into four categories based on their risk type – Class A, B, C and D, where A and B covers low-risk devices such as diagnostic equipment and C and D cover high-risk devices such as implantable devices. It was notified that the central agencies would be involved in approving devices in C and D category.

Where they exist, the Bureau of Indian Standards (BIS) product standards are to be followed. Where these are not available, those set by the ISO or IEC should be observed. However, the BIS still continues to have certifications that are relevant for low-tech devices, with all remaining devices borrowing product standards from either the ISO or IEC, pointing to an ever-present lacuna in policy preparedness, awareness and foresight to customize standards and incentivize indigenous, innovative manufacturers. There were further issues with medical device regulations and policy framework that created challenges for technological capability development for Indian industry. These are discussed in the next section.

### **3.6 Problems with Medical device and diagnostic regulatory frameworks**

The passing of Medical Device Rules, 2017 did not alter categorization and treatment of the medical devices and Diagnostics as drugs and continued mismatch between regulation and products. The inadequacies of MDR 2017 soon became evident as approximately 5,000 medical devices are sold in India, but only 23 categories of them are “notified” and consequently covered in regulation (Nath 2019).

There are still three significant issues with the new medical device regulation; the first pertains to the division of regulatory enforcements power between the state and central agencies while the second relates to categorizing of devices and diagnostics under Drugs and Cosmetics Act, 1940 and third is concerned with governance structure for the implementation of the regulation.

First, of note is the role that states play in sales/distribution licenses for all classes of drugs. When it comes to manufacturing licenses, low-risk devices (classes A&B) are under states’ purview, whereas higher risk devices (C&D) sit under the Central Licensing Authority. This division of responsibilities between central and state agencies has led to issues of creating appropriate incentives for innovation, additional delays and roadblocks and lack of capacity at the state and central level to monitor class C&D devices.

Second, it is argued that the medical devices and diagnostics need a new regulatory act rather than modification of an existing act designed for the governance of drugs and cosmetics. As Rajiv Nath (2019), Forum Coordinator of the Association of Indian Medical Device Industry (AiMeD) has specified that within diagnostics and devices as well, there are

a wide variety of products and “you can’t have the same penalty for a manufacturing failure of a pair of spectacles as for a contact lens or for an intra-ocular lens. Patient safety is more complex with devices where the same are a shared responsibility of the manufacturer, medical practitioners, product user and the regulator.” (Ibid.) Further, the dynamic field of medical devices and diagnostics expands and includes diverse areas that were traditionally not considered part of the medical sector. For example, AI, mobile phones or blockchain technology are new areas driving the development of new diagnostics and devices. As a result, there is a need for regulation that allows this scope for evolution by the inclusion of diverse areas and the current D&C Act might prove to constrain the growth of the field.

A third critical issue concerns the governance structure set up to implement and interpret the rules as the existing regulatory system is proving to be inadequate. In some instances, the existing system has resulted in MNCs flouting standards by pushing “pre-owned” or “second hand” medical and diagnostic medical equipment to be used in private clinics and hospitals with no assessments done on their levels of accuracy or safety (Sheriff 2019). The case of Johnson & Johnson faulty hip implants highlights the problem with Indian regulatory architecture. Johnson & Johnson has failed to trace 3,600 Indian patients of the 4,700 who received a toxic hip implant marketed in India even after eight years of the product being recalled globally and has not paid compensation to even those who are now on its records. Based on this example, Sheriff (2019) argues that the Indian medical device regulatory architecture suffers from gaps such as poor standards for adverse event reporting, the culture of reporting adverse-events and poor-quality reports and therefore, needs a complete overhaul.

It is clear that the (pharmaceuticals and vaccines regulations) baby does not need to be thrown out with the bathwater, but the sub-sector differences to that of medical devices must be considered and defended where needed. After all, unresolved regulatory challenges within pharmaceuticals - such as price regulations and competitiveness - often remain for medical devices and will need a careful analysis of whether the same rules work or something else is needed.

Moreover, the National Health Mission, particularly the Free Diagnostic Service Initiative (FDSI) in India, provides further rationale for a robust regulatory framework and investment strategies for medical devices and diagnostics. However, the industrial policy incentives, guidelines, and regulatory roadblocks remain problematic according to the Association of Indian Medical Device Industry (AiMeD) which states that “key strategic aspects of the Road Map discussed with the Indian Medical Devices Industry Associations are missing” (Nath 2019). AiMeD seek the regulation resembling not the permit system of India’s pharmaceutical regulatory environment (what Srinivas 2012 refers to as the First Market Environment) but rather seeks regulations that mimic “international best practices of voluntary compliance” (Sarin 2018).

### 3.7 Step 3 Firm-level case studies

Three brief case composites from interviews are described here, conducted with start-up firms in medical devices and diagnostics. The composites created offer anonymity but also the context in which technological advances occur in specific regulatory contexts.

Firm A is an instrumentation specialist firm originating in public sector research laboratories and an associated university research ecosystem. Firm A helps improve the screening and treatment strategies for a type of cancer by improvements in optics instrumentation and relying on advances in a sub-domain of physics. Firm A is new to the market, with extended prototyping underway. Firm B is focused on combining multiple organizational and technology innovations which enhance Point of Care (PoC) quality of service. This increases the likelihood that patients seek care more routinely because the threshold costs are lowered. Firm C is start-up involved in developing Point of Care diagnostics for detection of non-communicable diseases (NCDs), anaemia and monitoring wellness parameters. Firm C is focused on creating diagnostics that are portable, easy to use and can be used in a resource-constrained environment. Firm C has received an award and recognition from the WHO for one of their devices and was recently taken over by an MNC.

Firm A faces the following regulatory challenges which are lagging its technological capabilities:

- i. It faces unclear regulations about the access to tissues and patients. The ecosystem of clinics and hospitals-and its ecosystem of clinics, hospitals to access patients- is shaped by regulations created with good intentions but unclear processes in fast-changing contexts about ethics, documentation, and approval timelines. (In terms of triad domains, 1 shows progress but 1 and 2 are delinked)
- ii. The burden of proof for its products and services are regulated by clinical trials requirements designed primarily for pharmaceuticals approvals. (1 and 2 of the triad are linked by regulations written for pharmaceuticals)
- iii. All three firms, unlike pharmaceuticals or vaccines which have no components, medical device and diagnostic instrumentation improvements, are often dependent on materials, size of instruments, and different scale and accuracy of measurement considerations of component elements. The compounding of accuracy or errors of component instruments and parts use a single product or process regulations that serve other sub-sectors. (There may be multiple operational triads for components of devices and diagnostics. For instance, a ventilator or a CT-scan may have many parts, each of which has a different set of regulations governing their presumed relationship of 1 with 2, or 1 with 3).
- iv. For all three firms, procurement guidelines for hospitals to buy such instrumentation have no adaptability in modifying the procurement process to address institutional change. This may mean encouraging buyers to comply with approval guidelines but at the same time providing incentives such as subsidies or scalable bulk orders that recognize a medical device or diagnostic's novelty, speed of solution, or ability to address an urgent problem. This leaves firms to accumulate the experience or expertise to negotiate, manage the procurement while satisfying the business imperative. For entrepreneurs of start-ups, this can become a burden. (explicit subsidy hurdles to 2 exists that complicates the tie between 1 and 3)

- v. Public hospitals, despite priorities for low-cost diagnosis and treatment, do not help these firms in medical devices and diagnostics any more than private hospitals do. Their systems may offer potential network benefits for firms if they successfully win a tender. In practice, the process may be cumbersome and opaque, making it simpler to negotiate with single private institutional buyers at a time. (public access rationale for linking 1 and 3 may be so cumbersome that firms in 1 may need to seek private firms in 2 directly).
- vi. Firms such as B and C that have many innovations in principle should be well rewarded. But business organization improvements such as Point of Care (PoC) improvements that enhance the screen and treat turnaround time to instrumentation innovations, as well as technological innovations in both hardware and software, are even less likely to have a clear benefit from regulations designed for pharmaceuticals or vaccines. (more innovative firms in 1 do not necessarily experience greater reward; more innovations seem to complicate relations of 1 with 2,3 rather than reduce them).

For composites of firms A, B and C, regulation lags behind their technological innovations. They are innovative and their products and services potentially beneficial, but challenges are considerable to such firms to cross the existing regulatory hurdles and customize their guidelines and approvals process to ensure a speedier interface to good healthcare outcomes.

#### **4.0 Analysis and discussion: E-I methods heuristics and the medical devices and diagnostics subsector**

The Indian medical device and diagnostic industry have been hampered by inadequate trade, industrial and regulatory policy frameworks. Table 3 presents key policy challenges and their impact on the development of technological capabilities.

This table highlights that the inadequacy of the current regulatory framework, a tax structure that incentivizes imports against indigenous manufacturing, procurement rules favour MNCs and failure of DPCO to resolve affordability issues. Imports are expensive and impact the availability of low-cost, effective, safe, and locally suited medical devices. Our analysis suggests that medical devices and diagnostics have had an unclear relationship between innovation and affordability for at least four reasons: there have been no clear price regulations until recently that forced suppliers and retailers to drop their prices; the institutional domain of industrial policy for medical devices is arguably nascent, and policies that shape innovation are delinked from those of pricing; the medical devices sector has minimal procurement and insurance which can narrowly direct suppliers to designated pricing segments; and the diverse types of firms and non-profits in medical devices offer varied pathways to pricing with some hospitals and clinics even providing entirely free medical devices and related healthcare.

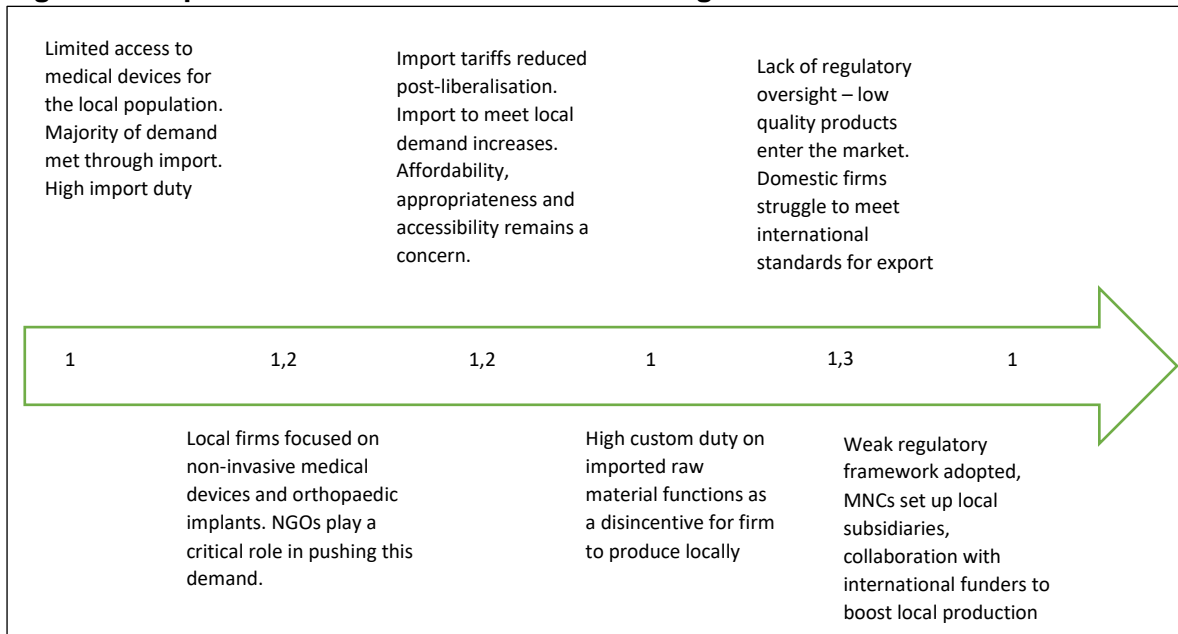
**Table 3** Interaction of 3 institutional domains in 3 health sub-sectors

<b>Triad institutional domain</b>	<b>Indian pharmaceuticals</b>	<b>Indian vaccines</b>	<b>Indian diagnostics</b>
<b>1 Production</b>	FME strong public sector capabilities and state-led domestic demand; SME strong private sector capabilities driven by overseas demand.	From FME and through SME, Indian vaccine manufacturing and R&D capabilities originate in strong state-led public sector push and increasingly shift to private sector	Some state-led activity and public research but no equivalent industrial supports or infant industry protections similar to pharmaceuticals and some vaccines. Unlike essential pharmaceuticals and many EPI vaccines, the majority of medical devices and diagnostics imported.
<b>2 Delivery</b>	Delivery increasingly driven by secondary and tertiary care	Public and private health system provide essential vaccines, largely through primary health care	Public and private hospitals, nursing homes, and clinics
<b>3 Demand</b>	Foreign welfare states especially of USA and Western Europe provide strong demand for Indian pharmaceuticals	International and national procurement direct the technical safety and quality upgrading of vaccine manufacturers network	WHO guidelines for regulation exist, but not procurement systems. The current procurement rules based on firm size are not conducive for start-ups and emerging local firms and mostly favour MNCs.

(Srinivas 2012; Kale 2019)

In the pharmaceutical sections, we assessed how the triad might be depicted through a chronological event of snapshots depicted along the dominant trajectory of the sub-sector. These were shown as points along an arrow. We apply the similar triad heuristic to analyze Indian medical devices and in vivo and in vitro diagnostics and as the sections have shown, very different challenges ensue (see Figure 3).

**Figure 3 Snapshots of the medical device and diagnostic industries**



Source: Adapted from Srinivas (2012, 8) by the authors

This indicates that the most notable gaps for medical devices compared to pharmaceuticals and vaccines are three-fold:

- i. Significant differences with pharmaceuticals and vaccines on the production side, with large imports continuing and growing but unevenly regulated domestic technological capabilities;
- ii. Significant differences in demand support: lack of large single institutional procurers whether domestic or foreign such as those that exist with pharmaceuticals and especially with vaccines.
- iii. Absence of strong infant industry protections alongside upgrading requirements similar to the First Market Environment and Second Market Environments for India, but strong price controls being introduced on certain types of devices and diagnostics before this type of demand opportunity exists. On the other hand, with a spreading coverage of state-level and central health insurance schemes, greater coverage of medical devices in contrast to the experience of pharmaceuticals and vaccines.

In such a framework, the distinctive learning paths of pharmaceuticals and vaccines can be explained through different institutional arrangements built over time that not only forced the market conditions and non-market institutions to closely cohere, but also resulted in industrial and health policy instruments moving closer together. For example, welfare procurement markets shaped Indian generic drug manufacturers in ways different from vaccine manufacturers and international institutional procurers. These specific differences in two different manufacturing domains – generics and vaccines – reveal findings of the importance in differentiating between the traditional economics of industrial policy design and becoming improved manufacturers, and the institutional reform and slow learning required to modify innovating, growing, and mature, established elements of manufacturing (Srinivas 2019).

#### 4.1 Discussion: Institutional Learning in the Indian health industry

This paper has viewed regulations as a fundamental aspect of industrial policy's selection effects on the institutional variety that exists in any sector, and which shapes the learning environment of firms. The experience of the medical devices sub-sector in India was analyzed for the first time in contrast to the country's pharmaceuticals and vaccines experience, through emphasizing the potential for evolutionary-institutional methods and their insights. Consistent with prior scholarship on Indian pharmaceuticals, the analysis of medical devices and diagnostics reveals several dimensions of institutional learning challenges that remain in India, arguably, one of the late industrial world's most successful example of R&D and manufacturing success. These challenges include:

- i. Technological capabilities in medical devices has emerged into a regulatory environment that was designed and equipped for pharmaceuticals
- ii. These capabilities although pronounced for R&D and manufacturing has struggled without the institutional learning environments of demand (insurance, procurement) or delivery (close ties to clinics and hospitals or required use in primary health care).
- iii. State-led intervention is notably absent in this sub-sector relative to pharmaceuticals and vaccines despite the sectors potential health impact. Kale and Wield (2019:19) point out that setting industrial policy for medical devices is extremely complex compared to pharma-biotech as it requires the involvement of a wider range of distinctive health institutions, regulatory institutions and industrial institutions. Where state-led intervention does exist, it is accompanied by a desire to regulate the sector without equivalent protections and direct infant industry or subsidy rewards as in the case of pharmaceuticals or established procurement channels for vaccines.
- iv. Despite innovation being high in the Indian medical devices industry, there is no clear correlation between state-initiated policies to reducing production costs or to consumer outcomes to increase affordability and access.

It is evident that methodologies that attempt different institutional combinations offer possible traction for such an evolutionary analysis. Most institutional change studies either approach the issue through formalism and econometric models which make it difficult to capture the change in progress or countries for which data is emerging or whose institutional environments are significantly different.

The evolutionary, institutional perspective of the heuristic shows that industrial gains in manufacturing do not reflect a steady march to a finish line. Rather, cross-sector effects, loss of capacity over time, challenges of organizational adaptation, regulatory selection mechanisms, and survival of firms, all pose distinct challenges to both the conceptual framework of economics and to the policy design relevant to a dynamic industrial organization in healthcare. As even industrialized countries demonstrate, there exist real challenges of loss of technological capabilities and the production political economy to nurture and retain capabilities (e.g. public sector vaccine manufacturing in the Netherlands, affordable medicines or suitable screened and tested devices in the U.S). For firms and policy makers, difficult questions emerge even in successful cases of production capability. The challenges are two-fold: to consolidate the manufacturing or R&D gains and ensure that they are converted into health gains, which is no easy task; second, to guide a "health



industry” in terms of regulation, governance norms, and export revenues, but to attend to the practicalities of diverse sub-sectors in this industry.

However, a country’s regulatory framework plays a vital role in addressing local health priorities, incentivizing firms, and ensuring patient access to new technologies. The promotion of global harmonization can undermine the role that nation-states and national authorities should play in devising a regulatory framework suitable for local conditions (Kale, 2019). It is interesting to note that out of the five countries/international agencies involved in the setting up of GHTF; Japan is the only country to incorporate some parts of the technical standard requirements recommended by the GHTF into its legal order (Altenstetter, 2014).

There are other arguments for customization of regulatory design. Medical devices need to be designed in a manner that is contextually appropriate - nearly all devices present in developing countries have been designed for use in industrialized countries. Up to three-quarters of these devices do not function in their new settings and remain unused. Factors contributing to this are lack of needs assessment, appropriate design, robust infrastructure, spare parts when devices break down, consumables, and a lack of information for procurement and maintenance, as well as trained healthcare staff. These issues are part of a broader problem in many countries: the lack of a medical device management system.

## **5. Conclusion**

We began this article by seeking to understand uneven technological capabilities and the institutional readjustment from the regulatory design that select the differences in building capabilities in one industry sub-sector to another. While institutional variety is manifested in an evolutionary process of learning and dynamism in the industry, much more is required to understand significant differences across industry sub-sectors. Within-sector differences in the same country capture learning and rigidities in translating to other sub-sectors in the same industry. Second, industrial policy response may be out of sync within and across some sub-sectors more than others. There are wider questions to contextualize about medical devices and diagnostics as a high-impact sub-sector. There is clearly a need for an Act and regulatory architecture exclusively focused on governing devices and diagnostics. The political economy of late industrial development has pointed to the essential task of building deep technological capabilities in manufacturing and using industrial policy as a primary lever for development. Manufacturing has been seen to generate a strong foundation of iterative learning in industry sectors that lead to economic development. This iterative learning stimulates not only technical competency but also growing capabilities in institutional design, where the technological capabilities can be fully established to generate public benefit. This permits governments to help businesses initiate and expand critical industries that branch out and are increasingly embedded in the economy while generating dynamic new associated capabilities and sectors.

The differences of medical device regulations and the experience of the sector combined with heuristic “snapshots” and composite cases from interviewed firms demonstrate a preliminary approach to revealing different evolutionary, institutional features of sub-sector trajectories. By providing details of the three sub-sectors, we attempted to show how policy

instruments in the two broad institutional domains of industrial and health policies have had observable effects on the medical devices and diagnostics sub-sector, whose importance for India and the global health system has yet to be fully analyzed.

By focusing on opportunities to extend methods of evolutionary, institutional economics to contend directly with within-sector differences in learning and regulatory lag, the paper has attempted to offer some resolution for how one might systematically map the different combinations and pathways adopted by sub-sectors of one country's health industry. Rather than purely quantitative methods that lose much of the adjustment analysis and differentiation across sub-sectors, this paper was focused on directly building the microeconomics of the learning of firms, on the combinatorial challenges of regulation design and wider institutional change that industrial policy generates. By doing this, we can move from more generic questions about infant industry status to specific policy menus that have been historically considered at the nation-state, but which here could answer questions of particular policy reform, e.g. Food and Drug regulations. It has also made more evident the limited conditions in which an otherwise strong state that has assisted pharmaceutical and vaccine manufacturers has been far less helpful to medical device firms, raising the question of how regulatory "lag" can be minimized and who has the power to do so. Should neither consumers nor the state but medical personnel or industry associations influence the design of regulations and inducements to firms? And given the different periods in which specific combinations of the triad are evident in some sub-sectors and not others, what does it mean to have "domestic" industrial policy in a global market for diagnostics and increasingly global health guidelines on their use? As some of our ongoing India team research on the ICCA cervical cancer HPV vaccines indicates, if diagnostics are considered an essential part of the screen and treat alongside vaccines, they are quite different E-I starting conditions than if they are substitutes (Srinivas and Rao, 2020). Similarly, the triad strategy as part of a Systems Dynamics approach in E-I analysis can capture the geographic reach and market variety as core regulatory inducements in design. If diagnostic firms are successful exporters in highly restrictive markets, can domestic regulators in health as well as industrial policy automatically accept with few hurdles the technological capabilities and technical standards these firms represent or should more customization for local contexts be required?

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