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Coordinating innovation in generic-dominated pharmaceutical markets

A study on government coordination and R&D policy in the Indian pharmaceutical industry

Author: Jose Maria NERI PEREYRA
Supervisor: Per AGRELL
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Foreword

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Thank you all for being my pillars.

Abstract

The pharmaceutical industry is characterized by its deep complexity and unique attributes. A pharmaceutical supply chain requires adequate coordination mechanisms to ensure optimal production, distribution, and innovation. Innovation in this industry is paramount for global health, but implies facing thorough regulations, quality compliance, high R&D expenditures, and high uncertainty. Countries like India achieved the development of their industry by historically leveraging capabilities in the production of generics. In fact, 20% of the global demand for generics is supplied by India. However, efforts to encourage the development of innovative drug therapies have not led to a diversification of product portfolios, as Indian firms continue to focus their efforts on R&D destined to generic production. Thus, a novel governmental coordination strategy to transition from a purely generic-based pharmaceutical industry to one that also fosters breakthroughs is imperative. This work combines theoretical resources with a comprehensive case study on India to gain insights on market dynamics, governmental policies and key conflicts of interest. A cost-sharing coordination contract was identified as a mechanism to achieve optimal production levels and R&D capacity build-ups, which model the investments allocated to R&D efforts. The findings suggest that the cost-sharing mechanism optimally achieves capacity build-up through the R&D phase in a context of full screening, as hidden information leads to efficiency losses. To ensure authentic innovation, it is imperative for high-level prices to align with marginal costs, thereby hindering the attainment of optimal R&D capacity. Hence, the results demonstrate the importance behind full screening of patents in order to achieve the objectives behind government investments. Only through this approach can resources be allocated appropriately and efforts be steered clear of misdirection.

Keywords: pharmaceutical industry, innovation, generic drugs, government coordination, R&D, India, patents, cost-sharing.

Contents

1 Introduction

1.1 Motivation

Pharmaceuticals distinguish themselves from most products by many intrinsic characteristics, challenges, and complexities. These products face rigorous regulation, quality compliance, risk management, and uncertainty. Yet, pharmaceuticals remain vital goods to every economy in the world which is why the industry is worth US$1.48 trillion as of 2022 (Mikulic, 2024). The history of the pharmaceutical industry is marked by great achievements and challenges. One country that stands out among the rest is India due to its massive pharmaceutical industry not reliant on innovation. Their industry is considered by many as the beacon of generic drug production, supplying around 20% of the world's generic medicines in volume (Green, 2023). The country's industry is worth US$ 50 billion and is expected to reach more than US$ 100 by 2030 (Invest India, 2024). India represents the core around which this research is built due to its particular positioning. One of the main characteristics of the Indian pharmaceutical industry is that it is composed mainly of so-called "branded generics" (Fitch Ratings, 2023). These firms differ from pure generic manufacturers, they produce off-patented drugs under their brand name and have also begun to venture in innovative drug development. Around 75% in volume and 90% in value of the Indian pharmaceutical market share is composed of branded generics (Fitch Ratings, 2023). The success and growth of branded generics developments over the past decades resulted in an increasing number of these firms engaging in innovative drug development. For this strategy to be successful, it may require a shift in the country's positioning as the major supplier of generics to a hub for pharmaceutical R&D and innovator products.

To address the development and success of innovator pharmaceutical products the Indian authorities needs suitable coordination with branded firms. The focus on the country is without loss of generality as it is often considered the reference for generic pharmaceuticals and describes the reality of many countries with developed generic industries. This would encourage the development of innovative drugs while maintaining the country's stance as the reference of drug availability and affordability. Optimal coordination of operations is essential and is usually studied across different all stages of a supply chain: procurement, production, and distribution. Allocating the right resources within the agents partaking in the value chain is paramount to guarantee each party is properly remunerated and incentivized. Coordination contracts have been studied extensively in the context of supply chain management; they allow optimizing channel performance and provide suitable information and incentive mechanisms (Cachon, 2003). They are typically used to model the relations between retailer, manufacturer and/or supplier. Contract theory is the general branch of economics that studies how economic actors engage with each other by constructing contractual arrangements and designing mechanisms that optimally align incentives (Bolton & Dewatripont, 2004). Supply chain coordination contracts rarely focus on the interaction with agents that are not intrinsic members of the supply chain, as governments for instance. These agents can be influencial on decision-making as they can impulse or hinder activities. The mechanisms used, be it buyback prices, cost-sharing, or revenue-sharing, provide interesting insights as to what can be applied when a government interacts with a branded firm. This research aims at analyzing the Indian pharmaceutical industry and providing recommendations on how R&D for innovative products can be supported.

1.2 Research question

This work aims at exploring government-based coordination of innovator product development in a pharmaceutical industry with predominantly generic producers. This subject is of relevance for countries such as Brazil and India, which possess important resources in infrastructure and knowledge capital, and industries mainly consisting of generic production. The focus is made on India by examining the historical backdrop, alongside the current challenges and interplays. Coordination contracts represent the necessary toolkit to approach how the interactions with firms are conducted when considering the pharmaceutical industry. The case study of India provides detailed market dynamics and its findings help construct a model to analyze government investments and financial support.

The primary aim of this work is to provide recommendations instead of definite solutions. It acknowledges the complexities of policy-making which are inherent to each country and serves as a basis for strategies supporting innovation in pharmaceuticals. Hence, the research question around which this work is constructed is as follows:

How should government-based coordination in generic-predominant pharmaceutical industries be conducted to foster innovation?

This principal research question can be decomposed in further sub-questions that ultimately build the research. They guide the exploration around how the Indian government could enhance its role as a hub fostering innovation.

- What is the current state of the pharmaceutical industry in India, and what historical insights are important to consider when promoting innovation?
- What are the market dynamics regarding branded generics, innovator products, and government support.
- How can these relations be modeled to achieve optimal production quantities and affordable prices
- When innovation comes from already-established branded generics, does the government face disadvantages when failing to distinguish the type of investment?

2 Review of incentive conflicts and coordination mechanisms in pharmaceuticals

Strategic objectives often differ between agents in any economic setup. This is also the case for a pharmaceutical industry subject to scrutiny from public health authorities. To understand how coordination can be achieved, it is helpful to first comprehend how conflicts arise in a pharmaceutical industry and how they are resolved. Coordination contracts identify a paradoxical behaviour between governments and firms and implement mechanisms so these conflicts are internalized by all parties. Pharmaceuticals differ from other products due to their intrinsic nature as essential medicines and their importance regarding public health (Moon *et al.*, 2011). These goods represent an essential pillar in all economies and the demand for them can factor a large profit for firms, which is why a trade-off is necessary between wealth and health (Maynard & Bloor, 2015). Moreover, there is a large interest for middle- to low-income countries to develop their own pharmaceutical industries, which contributes to international health care by balancing it with industrial goals (Da Fonseca, 2017).

2.1 Conflicts of interest in a regulated-goods industry

When monetary interests conflict with public health objectives, all parts of the supply chain, from sourcing to distribution, can be affected (Rodwin, 2019). Newly developed drugs are sometimes introduced into the market with not enough testing from public authorities nor evaluation on the quality of innovation (Abraham, 2002). Public health policies must balance several factors. Having an informed policy-making often implies working with experts in the private sector, experts who can have ties to pharmaceutical firms (Rodwin, 2019). In distribution for instance, agents vary from hospitals, private distributors to even public authorities. Financial ties between these agents and pharmaceutical firms or even intermediaries can exist, they imply that when deciding quantities and/or prices, the parties might follow interests that diverge from public health objectives (Rodwin, 2019). Indeed, a pharmaceutical firm's focus on profit maximization can endanger public health as interests increasingly misaligned (Brezis, 2008). One reason for the extent of this misalignment is the information gap that exists between pharmaceutical firms and other actors (Brezis, 2008). This last statement is not limited to a doctor-patient relationship, but rather generalized to a vendor-purchaser one. Conflicts of interest in a pharmaceutical setup arise in many different forms,from illegal promotion or production of drugs, patent wars, bias in research agendas, insufficient quality of innovation, insufficient published evidence or even production preference for high mark-up drugs (Brezis, 2008). Among the most concerning activities derived from conflicting interests is market manipulation through high prices or under-supply, because of the essential nature of these goods, (Bonitatibus, 2023). This does not mean however, that high prices are necessarily bad, low prices can reduce R&D investments below levels that are socially acceptable (Ellison & Wolfram, 2006)

In a recent congressional report from the United States, pharmaceutical firms were shown to direct R&D expenditures to research aimed at extending monopolies and suppress competition while justifying high drug prices (Bartz, 2021). In a form of tacit collusion known as "Shadow-Pricing", pharmaceutical firms kept prices high with would-be competitors and extended already-existing monopolies, while cutting prices in other countries. This

phenomenon is predominant in the United States as the healthcare system is based around private expenditure.(Burns, 2023). Other ways to manipulate the market while protecting existing monopolies consist in controlling the patent system by preventing lower-priced generic products from entering the market (Nocera, 2017). Product hopping was also reported as an anti-competitive stratagem to deter competition where pharmaceuticals face a small change before generic competitors enter the market to switch product consumption and maintain market share (Brill & Advisors, 2020). This practice receives many different names, but ultimately relates to patent extension over specific active molecules. The pharmaceutical firm is subject to many antitrust issues and supply problems when it comes to patented drugs. As mentioned above, minor tweaks to branded molecules aimed at increasing patent life have also been called "evergreening" (Davey, 2022). Other reported anti-competitive behavior is pay-for-delay patent settlements, where generic manufacturers are paid by branded firms to delay their market entrance (Kades, 2021). From broader perspective, it would seem that the general pharmaceutical industry is based upon a never-ending face-off between R&D-based firms striving for extensive patent protection (Roemer-Mahler, 2013).

2.1.1 A driving element of conflicting interests: patents in Big Pharma

Some governments have managed to develop their domestic pharmaceutical industries by changing the traditional patent legislation. This was the case for India, where at some point only processes could be patented for 5 years and not end-products (N. Kumar, 2003). By allowing firms to research other processes to produce the same drugs, the country went from importing most of its pharmaceuticals to properly supply not only its population, but also the global supply becoming the "pharmacy of the world" thanks to its stance in patent law (Horner, 2019). India is known as a global supplier of generic medicines, however it still faces challenges related to production, innovation, and a need to maximize the social benefits of the industry (Horner, 2019). In cases where patents play a significant role in allowing proper pharmaceutical supply, the supply chain is studied with a minimum of two stages, an Active Pharmaceutical Ingredient (API) supplier and a Final Product (FP) manufacturer. The API supplier converts raw materials into APIs and the FP manufacturer brings APIs into their final form i.e. tablets, liquids, and so on. By studying the market in India it was observed that several firms possess capabilities across all stages explaining the important production output of the country. These firms are often regulated by the government on pricing and production quantities (Horner, 2019). It also implies that a game could be considered between a firm acting as FP manufacturer and seller and the government taking the role of a buyer.

Patents play an important role in addressing conflicting interests and the adequate supply of pharmaceuticals. They determine when and whether generic producers can enter the market. Firms often relentlessly attempt to extend existing patents. This was the case with AstraZeneca an their attempt to change a drug "Prilosec" to a new one "Nexium", all while keeping the same active molecule (Brezis, 2008). Typically, pharmaceutical firms benefit from patent protection by recovering the expenses in R&D through high prices. Once generics enter the market, prices drop by 90% (Tu, 2022, as cited in Roberts, 2022). This also implies that prices between new drugs and already-existing ones should differ by this amount while guaranteeing affordability for innovative drugs. In some humanitarian contexts, firms have been known to share patented compounds to address neglected diseases (Rosoff & David, 2011). Poor countries have also received permits to produce low-cost generics through special licensing (Rosoff & David, 2011).

Da Fonseca (2017) demonstrated that voluntary licensing is possible even for several different products within a single country. In these cases, firms have seen beyond diverging interests and focused on humanitarian goals. Drugs can and are very often subject to differential pricing, specially when it comes to the supply of impoverished countries. This was the case with HIV/AIDS treatments during the AIDS pandemic (Pauly & Danzon, 2002). However, firms have been commonly reluctant to conduct these type of humanitarian actions, due to issues such as cross-border leakage of low-cost drugs (Pauly & Danzon, 2002).

2.1.2 Patents at the heart of an innovation-affordability conflict

This literature review has exposed some recurrent conflicts in the pharmaceutical industry. Innovative firms against generic producers, branded firms against governments seeking national welfare. From a legal standpoint, patents are governed under the Trade-Related Intellectual Property Rights (TRIPS) by the World Trade Organization, the most comprehensive multilateral agreement (WTO, 1995). TRIPS have been however criticized as having adversely impacted access to pharmaceuticals in poor countries that do not have the necessary production capabilities (Verma, 2019). These countries must usually rely on licensing to import generic drugs. Licensing that may allow imports without the patent holder's consent. The TRIPS Agreement allows granting these licenses under a case-by-case determination. Usually to address circumstances of extreme urgency. Pharmaceutical patents can be regarded as primary or secondary. Primary patents are the most important ones since they protect compounds from early R&D stages up to decades after production has begun. They also prevent generic manufacturers from reverse-engineering novel compounds (Dai & Watal, 2021). Process patents, also known as secondary, as those used in India, do not guarantee market exclusivity, which is the main reason why India became the largest generic drugs manufacturer (Dai & Watal, 2021).

Public interests call for a proper supply and affordable prices, while pharmaceutical firms strive for extended patents and high drug prices to finance future R&D (Xu & Zhu, 2020). Firms will seek to maximize the value of patent monopolies since it is more profitable for them, by increasing the length of patent protection, paying distributors to switch products, and so on (Jorgensen, 2013). However, if firms do not manage to bring sufficiently new patentable products, they might face revenue losses (Roemer-Mahler, 2013). Xu and Zhu (2020) studied the crucial nature of the patent system as an incentive to innovation and protection for both branded firms and generic manufacturers. It allows firms to venture into costly and often risky research, which they support through high prices. In the study, the patent system was also shown as a safe-space for knowledge-sharing with generic manufacturers through mechanisms such as cross-licensing, where firms can hold part of a patent and thus bargain in profit distribution. The ultimate aim being the search of a balance between innovation and public health. The results imply that innovation is promoted through patents, and regulation of prices must be achieved through taxation (Xu & Zhu, 2020). More specifically, the authors showed that by progressively taxing both branded and generic firms, the two types of firms coordinate between them on drug pricing to maximize their profit shares.

Compulsory licensing has been considered as the best legal mechanism to ensure access to pharmaceuticals, specially in times of crisis (Davey, 2022). In a recent paper, Davey (2022) argues that patent barriers not only affect countries differing in production capacities, but

also low-income populations inside rich countries such as the United States. Compulsory licensing refers to the permission from a government to produce a patented product or process without the necessary consent of the patent owner (WTO, 1995). Davey (2022) argues that the mechanism would allow a country to develop production capacities and generic manufacturers. India, as well as other countries such as Brazil or South Africa, empowered their pharmaceutical industries through compulsory licensing using their political leverage to bypass international patent regulation (Davey, 2022). The author also proposes other mechanisms, such as linking remuneration to global health impact via innovation prizes. Such measures would incentive pharmaceutical companies to improve societal health outcomes while increasing innovation and competition.

Now that this persistent struggle has been identified and categorized as an innovation-affordability paradox regarding innovator and generic drugs, this review will dive into the existing literature regarding pharmaceutical supply chain coordination. The goal being to understand how contracts are used, what are the specifics related to the pharmaceutical industry, and how contracts could solve patent-related problems for a government aiming at developing innovation under a historical policy of generic affordability.

2.2 Coordination mechanisms with pharmaceuticals

There is a great variety of literature on coordination contracts that align the motivations of agents within the supply chain. Some of these include the buy-back contract, revenue-sharing contract, or the quantity-flexibility contract (Cachon, 2003). It has been argued that Pharmaceutical Supply Chain (PSC) coordination brings added complexity and risk because of a population's healthcare system, the stochastic nature of demand, as well as the uncertainty of the R&D phase (Patel *et al.*, 2023). The vast number of stakeholders in this industry, combined with globalization, has led to an increased need of collaboration and coordination in the supply chains.

From a general coordination standpoint, PSC coordination can be modeled as a three-level supply chain: a manufacturer, a distributor, and a retailer. Such a model is applicable in the context of pharmaceuticals and more generally to products with limited shelf life (Arshinder *et al.*, 2009). The manufacturer is defined as the upstream member of the supply chain answering the demand coming from the distributor. The upstream agent incurs a production cost and sells each unit at a wholesale price which is related to the cost of bringing the product to production. The distributor acts as an intermediary and fulfils the order of the retailer while incurring a marginal sourcing cost and a goodwill cost for unmet demand. The last agent in the model, the retailer, orders its optimal order quantity to the distributor which is less than the optimal order quantity of the supply chain. The distributor thus pays the wholesale price, incurs a sourcing cost, a goodwill cost for unmet demand, and can also generate revenue by selling and salvaging unsold units. Such a model is a common representation of the relation behind a pharmaceutical supply chain.

Arshinder *et al.* (2009) analysed two types of coordination mechanisms to be used as decision-making tools when designing a contract between pharmaceutical agents, namely a Buyback and a Quantity Flexibility. The nature of these mechanisms becomes irrelevant upon

the fact that coordination has higher chances of being successful the higher the inter-dependency between supply chain members is (Arshinder *et al.*, 2009). To further increase the effectiveness of the mechanisms, the authors claim that parties should jointly choose the type of contract. Further, parties should also share the decision variables, cost and price information with each other, and conduct joint evaluation of performance measures. This reasoning could be extended towards the interaction between a government and a branded firm.

2.2.1 Contract challenges specific to the PSC

Typical coordination mechanisms, as those presented previously, need some specifics when applied to a PSC. Studying and understanding these contracts as well as the relations they imply between PSC agents, allows building coordination schemes that solve innovation-related problems. Foladi-Mahani *et al.* (2018) studied a mechanism tailored to a two-level PSC where waste must be avoided. The authors define a primary and a secondary production level. The primary level produces the perishable active pharmaceutical ingredients (API) which translates in an upstream member, namely the API supplier. The secondary production level formulates these active ingredients into final pharmaceuticals (FP) and serves as a supplier to customers, mainly drug stores and hospitals. The FP manufacturer is hence the downstream member of this business-to-business (B2B) supply chain. The model could be more insightful if it would consider a separate level for a distributor, since the FP manufacturer does not always have this role. The distinctive feature lies in the possibility to extend the shelf life of raw materials in the supply chain through retesting (Foladi-Mahani *et al.*, 2018). In this context, reprocessing is defined as a chemical process where only a percentage of the raw material will be able to be resold. The API supplier buys the surplus raw material at a buyback price from the FP manufacturer, lower than the original price paid. By reprocessing surplus raw material inventory, the API supplier can use it again in the next time period and sell it at the same original price (Foladi-Mahani *et al.*, 2018). In such a case, this mechanism could be applied when there is a mismatch in production quantity requested by a government and realized demand. It could also be of use in the case where a component is outsourced from innovative firm to a generic firm.

Just like any other industry, production disruptions are an unavoidable reality in the pharmaceutical sector. Defective batches, products, or raw materials must be recalled and modified which results in extra costs for the firms (Hosseini-Motlagh *et al.*, 2020). Whenever the API supplier faces a disruption, all affected products must be recalled. This affects the operations of the FP manufacturer and even distributors. These factors lead the downstream agents to under-stock due to increasing costs of recalling, according to Hosseini-Motlagh *et al.* (2020). In such case, coordination can be achieved through an altered revenue-sharing contract. The choice of an altered revenue-sharing model comes from the fact that the FP manufacturer's wholesale price can sometimes be determined by the government. The contract provides insights on the application of revenue-sharing contracts applied to the specifics of the operations of pharmaceutical firms concerning uncertainty. This contract also provides a mean to overshadow any increase in loss by recall due to a fluctuation of the wholesale price dictated by the government or authorities. The altered revenue-sharing contract prevents demand loss by setting a selling price independent of the FP manufacturer's wholesale price. It increases the performance of the PSC in the case of an increase in the API supplier's production cost. While specific to a B2B relation influenced by government policies, this

model provides an approach on how to apply revenue-sharing in the context of pharmaceuticals.

Another topic of interest is the reselling of leftover medications in alternate markets. Leftover pharmaceuticals not only imply additional costs for PSC agents, but also potential penalties from authorities, and less social welfare for the country. These medications can be collected from the retailer and resold in a secondary market prior to their expiration date (Tat *et al.*, 2020). Secondary markets can be neighbouring countries or deprived territories. This type of reverse logistics allows to cut losses in comparison to traditional pharma reverse logistics for product disposal by upstream agents, but requires the implementation of a coordination mechanism (Tat *et al.*, 2020). The contract also becomes interesting when considering aspects such as the implication of patents and the supply for low-income population in or outside a country.

The contract proposed by Tat, Heydari, and Rabbani (2020) covers a two-echelon PSC with a supplier, namely the FP manufacturer, and a retailer taking on the role of the distributor. The product is a fixed shelf-life medication requiring high service level. The coordination in this model consists of a buyback scheme that aims at reducing waste to avoid disposal costs and penalties. To convince the retailer to participate in the coordination structure, the scheme mixes buyback with a shortage risk-sharing mechanism. Indeed, the retailer's inventory policy aims at diminishing shortage risk because of the expected high service level. Realized demand allows the FP manufacturer, who is responsible for collection and disposal, to decide on the buyback quantity destined to the secondary market. The medication is bought back from the retailer at a wholesale price and sold in the secondary market at a price different from that of the primary market. In addition, the FP manufacturer pays a rate of retailer's shortage to incite them to enter the contract. This results in a percentage of the realized benefit from the secondary market shared with the retailer. Parameters influencing the choice of the bought-back quantity are the costs of reverse logistics, realized demand, and governmental penalties for remaining end-of-life medication (Tat *et al.*, 2020).

These initial models, applicable to a PSC, hint at the particularities of coordinating decisions in the presence of regulated goods. They explain the relations between upstream and downstream members and bring clues into more competitive settings. They also provide benchmarks on how traditional coordination mechanisms such as buy-back and revenue-sharing are to be applied to the specifics of pharmaceuticals. A government mindful of rightful drug supply for its population opens path for different dynamics applicable towards and among pharmaceutical firms and these mechanisms give hints on how to construct contracts.

2.2.2 Considering Corporate Social Responsibility (CSR)

Governments often impose recollection amounts of remaining or unwanted medication to FP manufacturers. If the recollection quantity is less than a threshold, the FP manufacturer will receive a penalty. On the other hand, if the quantity is higher, the FP manufacturer receives a subsidy (Hosseini-Motlagh *et al.*, 2021). After recollection, remaining medication can be sold at an alternate market, donated, or safely disposed. The FP manufacturer has since two sources of saving-cost. When reselling at an alternate market, it gains profit, and when donating it it receives a tax exemption. This translates into a saving-cost per unit. Similarly,

a comparable approach could be drafted to reduce R&D costs in the case where a government interacts with pharmaceutical firms. The contract is however specific to a certain setup with reverse logistics. It does so by increasing the CSR efforts provided by the distributors and by decreasing negative impact caused by unreturned medication left to expire. It is important to notice however, that higher cost for CSR efforts will translate into lower returned amounts and less efficiency of the contract. Alternatively, an increasing penalty or subsidy will cause the FP manufacturer to claim for higher returned amounts (Hosseini-Motlagh *et al.*, 2021).

Coordination on pricing and CSR efforts can also be achieved using a CSR cost-sharing contract where the retailer shares fractions of the CSR investments made by the two FP manufacturers. This means that by investing in a certain amount of CSR efforts, a fraction of the cost will be shared with the retailer. The exact values of these two fractions are computed using the respective bargaining power of the PSC agents, which yields results acceptable for all agents. The increase of demand coming from CSR efforts and lower retail prices allows this coordination contract to reach the PSC profit level of a centralized model (Johari & Hosseini-Motlagh, 2020). The limitation resides however, on the fact that pricing is determined by the distributor when in reality, patents imply that branded firms often fix prices, at least during the patent's life. Several facets of pharmaceutical coordination have been studied in this review, which allow a deeper dive into the role patents can have among agents' dynamics.

There is a vast amount of literature regarding coordination in the supply chain, which is also the case for pharmaceuticals. Surprisingly, very few address the innovation dimension for the latter. This puts further weight on the need for coordination schemes that consider the nature of these patent-protected goods, in the context of a developing R&D industry. This review has studied the relations between agents, whilst considering competitive scenarios that could be enlarged to the development and competition between branded generics in R&D. It has also considered a social responsibility dimension, much relevant if societal aims deriving from the availability of drugs are considered. The role of the downstream member of the supply chain can be generalized to that of the government, mindful to guarantee the availability of drugs, and seeking to maximize social health. It is now appropriate to further study the role of patents in contracts to understand how these are affected.

2.3 Protection of innovation and product availability

The existence of patents and its importance has allowed the emergence of a new type of supply chain in academia, namely the supply chain of innovation (Mazzola *et al.*, 2015). R&D becomes in this case a commodity, and the supply chain describes phenomena such as licensing. When am innovative firm (or a government) allows a generic producer to manufacture a patented drug, it is not a material flow taking place but rather an innovation flow. The term embeds all transactional relationships related to the purchase and selling of R&D commodities according to Mazzalo *et al.* (2015). These relations are varied and encompass licensing agreements, research collaborations, R&D joint ventures , co-patenting and so on. Mazzalo et al. (2015) brought attention to the fact that the supply chain of innovation must be considered separately from the traditional material-flow-related supply chain, specially for firms with high R&D activities. The contribution helps to keep a critical perspective when applying patents to coordination schemes.

2.3.1 Coordination in a patent-integrated supply chain

Literature integrating patents for PSC coordination is scarce. Wu *et al.* (2016) developed a cooperative R&D contract considering the quality of product innovation, which could be of use when considering a branded firm's innovation quality. The contract considers the outsourcing of supporting components in a collaborative supply chain. The firm in charge of supporting components acts as a supplier receiving a fixed payment from the manufacturer. The setup considers a common probabilistic product development success and innovation. The model uses a revenue-sharing mechanism between manufacturer and supplier, to reduce the risk of unethical behavior from the supplier. This would be possible by the fact that the supplier provides an unobservable effort to the production of supporting components. The conclusion of the study was that the optimal revenue sharing coefficient is negatively correlated to the manufacturer's input effort, but positively correlated to that of the supplier's (S. B. Wu *et al.*, 2016). However, if the manufacturer's has high probability of succeeding in the production of core components, then the supplier will provide a smaller effort. Interestingly, the model finds that the coefficient for revenue-sharing does not depend on the quality of the innovation, nor the fixed payment. The fixed payment is found to be positively correlated to costs, and inversely correlated to innovation quality. Innovation quality in this setup directly determines the market revenue, which explains these results.

The last model considers an R&D contract, and broadens the scope to the relations where patents could be shared between innovative firms and generics i.e. separation between core components and supporting components. Some contributions regarding patents in supply chain coordination have been recently made and they consider close-loop supply chains i.e. supply chains with forward and reverse flows. Zhang and Ren (2016) developed a coordination strategy with three agents: an original manufacturer, a third-party re-manufacturer, and a retailer. In the study, the original manufacturer possesses a patent and can authorize the work of the third-party manufacturer without engaging in the re-manufacturing process itself. Both firms incur costs, and sell at wholesale prices to the retailer, who in turn sells the product at different prices to different market bases. The original manufacturer charges a licensing fee to authorize the re-manufacturer's work. Other variables related to the study are a price for recollection, return quantity of used items, and a unit salvage value. In a dynamic game, the wholesale price from the original manufacturer as well as the licensing fee are chosen first to maximize the manufacturer's profit; re-manufacturer and retailer then follow.

The supply chain scheme presented by Zhang and Ren (2016) contributes with a novel revenue-and-expense sharing contract, where profits, losses, and external expenses are shared. Patent licensing fees however are not shared, but it is of little importance since the application of the contract induces the manufacturer to not charge them to the re-manufacturer. Resulting prices, both wholesale and retail, are lower, but higher market share and competitiveness are created (Zhang & Ren, 2016). However, the contract fails in maximizing the original manufacturer's profit who, as the leader of the supply chain, may choose not to engage. The buyer pays the seller a fixed fee and a constant charge for each unit purchased (Zhang & Ren, 2016). The authors consider a per-unit patent licensing fee and a qualification fee, which allow the seller to capture residual surplus. This mechanism is included into the revenue-and-expense contract; allowing for coordination in this patent-integrated supply chain. It remains relevant to a setting where innovative and supporting/generic firms are clearly

separated and distinguishable.

The topic has been extended recently by Jian *et al.* (2023) where the authors include consumers' environmental awareness. This model also considers a cost for re-manufacturing design, while taking into account patent protection and carbon emissions. Coordination is achieved through a cost-sharing contract where a portion of the re-manufacturing cost is shared between agents (Jian *et al.*, 2023). The re-manufacturer still pays royalty, though shares the cost of re-manufacture design. Another contribution is the positive outcome from implementing carbon taxes since it can encourage environmental responsibility and lower license fees from the manufacture promoting participation of the re-manufacturer. This scheme becomes interesting as it could be generalized to a tax implementation encouraging participation of the generic drug manufacturer, as well as a cost-sharing mechanism for situations where the generic drug producer might need to incur a cost as to re-engineer the manufacture process. However, the target coordination scheme in this research must consider first and foremost the cost of building-up the production which relates to the R&D phase that pharmaceutical products face.

2.4 Relating capacity reservation contracts to the R&D phase

Capacity reservation games are widely available in the literature. Similarly as the cases presented in the last section, capacity reservation games usually consider the dynamic between a supplier and a manufacturer in one demand period where the end-product faces some uncertainty and is dependent on a certain component provided by the supplier. Cachon (2003) presented a general setting for this game. In the first stage, the manufacturer (buyer) would provide the supplier (seller) with a demand forecast over a product. Having received the forecast the supplier would then build-up a capacity with a per unit capacity cost. The second and last stages imply production and remuneration, final production quantities are determined by the minimum between built capacity and realized demand. Hence, the proper capacity must be coordinated so that the final decision is neither too low nor too high. The uncertainty considered by Cachon refers to the demand forecast. The opposing incentives involve the possibility that a low-demand manufacturer would present a high-demand forecast to obtain more build-up of capacity and ensure all realized demand is satisfied (Cachon, 2003). Some of the solutions presented by the author to achieve coordination involve the use of options, buyback, as well as forecast-sharing, and dive into the cases of voluntary and forced compliance.

Li and Liu (2021) explored simple coordination contracts for the capacity procurement model involving asymmetric information. In their research, the manufacturer possesses private information over the demand and cannot commit to a final order since the product is being defined. The research also provides an interesting approach by using response functions that model the strategies of the players. The strategy of the manufacturer is modelled through a function determining the forecast reporting based on the real forecast. The strategy of the supplier is based on the forecast reporting, and outputs the capacity to build. Once the capacity is built, demand is observed by the manufacturer and the final order is placed. Again, the model describes the case where it is the manufacturer who hopes, using the information asymmetry, to their benefit by providing an over-optimistic forecast. Using a wholesale price contract creates an incentive problem and would also imply that the supplier bears the full cost of building the capacity up and thus the full risk of unsold units. To solve this, either a linear

capacity reservation contract is established, where the manufacturer pays for each unit of built capacity, or a payback contract that involves paying for each unit of unused capacity (Li & Liu, 2021). These mechanisms serve as risk-pooling contracts that achieve internalization of capacity excess or shortage.

Koo (2022) explores a capacity cost-sharing contract with further considerations, for instance risk-aversion and bargaining power. Demand uncertainty remains the main source of information asymmetry. The usefulness of this contribution lies in the mechanism that allows to internalize the cost of building-up the capacities by both parties. Bargaining power is used to determine an optimal wholesale price that is then used to compute an optimal capacity cost-sharing ratio. Risk-aversion is considered separately and from the supplier's perspective. This new model seeks to maximize the supplier's expected profit while constraining the standard deviation of the profit to a certain threshold. It is in fact the standard deviation of excess capacity that determines the standard deviation of the profit. The solution finds the combination of wholesale price and cost-sharing ratio algorithmically until no improvement is observed and the constraint is satisfied (Koo, 2022). Risk-aversion is also investigated by He *et al.* (2017) who consider the Conditional Value-at-Risk criterion to model risk aversion for potential losses. In this model, the manufacturer is responsible for R&D of the product and sells the products during a single season. To coordinate the supply chain, different options are explored as well as payback contracts. The capacity reservation contract is also considered, where the manufacturer pays a certain price per unit of capacity built (He *et al.*, 2017).

2.4.1 Considering sources of information asymmetry

While the literature for capacity procurement games is vast, it usually considers that the source for private information comes from the manufacturer's side, who supposedly knows the demand better and distributes the end-product. The literature does not necessarily consider the case where the source of uncertainty relies on the quality of the capacity. This issue becomes more compelling when the quality of the end-product determines the returns obtained through sales. Information asymmetry is highly common in buyer-seller relations and more generally in principal-agent relations. In what concerns patents, the innovation brought by the patent may very well be valuable, though it might also relate to already existing inventions and cover a simple improvement. Hence, the product in question might have a different cost per unit at the capacity level in R&D contexts. Schmitz (2021) delved into contracting under adverse selection. If we relate this to already-explored contracts as for instance cost-sharing, it might be the case that too low cost-sharing ratios might drive out sellers providing high quality capacity. Schmitz considers the case where the buyer is not certain as to how valuable the innovation offered by the seller might be and thus faces uncertain future revenue. The core of this setting therefore refers to an incentive problem on the seller's side (Schmitz, 2021).

2.5 Theoretical synthesis

This literature review delved into the topics of coordination applied to pharmaceuticals, patents, innovation, and societal considerations. These models provided important insights on how to represent the relations within the industry and how to apply mechanisms that achieve coordination. The review detailed conflicts of interest common in the pharmaceutical industry as well as sources of uncertainty or information asymmetry. Some of these being the misuse

of patents to extend protection over drugs, uncertainty on development phases, or even the disposal of over-production.

As to R&D, it has been modelled through different types of contracts and innovation incentives that are usually studied from the taxation standpoint. There is scarce research on how R&D costs of pharmaceutical firms can be shared either between firms or with authorities or how it can be modelled through the build-up of capacity. Cost- and revenue-sharing are commonly used as mechanisms to achieve coordination. Information asymmetry is also usually considered with the downstream party possessing the private information either on demand, forecast, or market access. Coordination contracts are usually considered between industry agents and not really between a government and a firm.

The interest for coordination schemes which consider the procurement of capacity is threefold. First, these coordination schemes provide an overview on a buyer-seller relation which comes useful when relating these contracts to the dynamic between a government and a branded pharmaceutical firm. Second, these games usually consider a firm-dependent ability to manufacture a product i.e. only the seller is capable of manufacturing a component. This last consideration becomes necessary when considering patent protection over products. Finally, capacity reservation games imply that the unique product goes through a phase of preparation before production. This preparation phase through which the production is not yet carried out, is analogous to the R&D phase pharmaceutical drugs go through in order to reach the final production stage.

3 Methodology

The following section aims at presenting the methodology behind this thesis. After introducing the main topic and challenges to be addressed, the literature review provided an overview on coordination contracts built around the pharmaceutical industry's dynamics. This provided an overview of mechanisms on how to coordinate and solve incentive problems deeply rooted within firms. The existing literature also hinted at the vast and diverse research concerning the complexities of the industry and how they can be solved in a firm-to-firm setting. It also allows the reader to better identify the key sources of incentive conflicts when it comes to the relation between firms and authorities as it is the case with production quantities, innovation, patents, and social dimensions. The review of existing research provides the necessary tools to approach a real-world scenario with data on specific government-branded firm relations, namely the case study of the Indian pharmaceutical industry. The analysis of the latter is done transversely and dives into the historical backdrop as well as current industry data. The primary factors within the industry are exhibited and analysed in order to understand where the principal conflicts regarding R&D incentives exist that have not been studied in depth yet. The case delivers evidence on the relations between industry players, i.e. branded generics, international institutions, and government institutions. The findings of the model are finally compared with the evidence provided by the case study to seek recommendations on how the development of innovative R&D in India should be conducted.

Commencing this thesis with a theoretical perspective of coordination mechanisms enables a resource-pool to understand the research context through a real-world case study. The goal of this work is to model the interaction between the government and pharmaceutical firms in an industry historically based on generic production. Branded generics began leveraging its capabilities, resources, and capital to provide innovation though innovation remains dominated by western firms. This research approaches incentive conflicts between the government and pharmaceutical firms. It implies to take an inductive approach as the focus is dependent on the observations from the case study. The theoretical framework of this research covers contract theory in supply chain coordination, incentive theory, as well as principal-agent theory. The case study is studied with the focus on incentives to understand what it would take for established branded generics to participate in the development on innovative pharmaceutical R&D of their country. Health economics is also considered as the focus is made on matching demand and supply of healthcare products for availability and affordability. The approach can be stated as analytical, based on objectivism and procedural rationalism, which is what we expect from a public - but not private-individual - decision maker. The Indian example provides "casual empiricism" without claims for exhaustiveness and detailed relevance of the stylized model. The conclusions are therefore general and qualitative, leading to insights into the consequences and limitations of certain stated or inferred policies and information structures. The research leverages the accessibility of public data, historic developments, official and professional statistics, to identify a core incentive conflict between parties. A theory is built around a real-world observation to describe it and provide guidance. This is constructed using the existing research on coordination contracts as a basis, and is tailored to the relation between the authorities and branded pharmaceutical firms producing drugs. The ultimate goal is to provide recommendations on government policy when it comes to promoting innovation while maintaining affordable prices.

4 An analytical case study on the expansion of India's pharmaceutical industry

The relations between authorities and pharmaceutical firms can be described by a broad spectrum of dependencies, challenges, and overall complexities. Some countries take a liberal approach regarding the pharmaceutical industry and allow the prevalence of high prices, since it aligns with the principle of free market. Other nations take into account the critical nature of these products, and some models are put in place to improve the access to medications. Three main models that have characterized the last decades are the Bismarck model, mainly established in countries from continental Europe, the Beveridge model used in Scandinavian countries, and the private insurance model in the United States. The Bismarck model is a mixture of private and public funding based on mandatory insurance and contributions, whereas the Beveridge model is built around taxation and a National Health Service (Lameire *et al.*, 1999).

The history of India's pharmaceutical industry can be considered to be greatly different from that of other countries. The model established in the country does not align with neither of the three models mentioned above. Traditionally, India leveraged its historical heritage, and its pharmaceutical industry was mainly based on the use of ayurvedic medicine (Aayush Sood, 2019). Generic producers were at first non-existent or rather unprofitable. The country's active patent legislation related back to the Patent Act 1911, which granted long patent life of 16 years plus extension possibilities of 10 years (Aayush Sood, 2019). This left no room for Indian firms to be active; the market was dominated by multi-national companies (Aayush Sood, 2019). In contrast, by 2017, the pharmaceutical industry of the country had grown to US $33 billion, with drugs being exported to 200 different countries making India the largest supplier of generic drugs worldwide (Akhtar, 2013). This section will provide an overview on how this transformation took place, and what interactions existed between the Indian government and branded pharmaceutical firms.

4.1 Historical perspectives and current developments

As previously mentioned, the initial patent regime of India related to the *Indian Patents and Designs Act of 1911* which was drafted by the British empire (Liu & Racherla, 2019). After India's independence in 1947, patent legislation was still imposed by the British, who asymmetrically benefited international pharmaceutical companies in comparison to the domestic industry, thus further hindering the domestic industry's development (Liu & Racherla, 2019). The year 1970 represented a major turning point for the Indian firms, as the *Indian Patent Act 1970* went into force. Under this new regime, national generic firms were encouraged to reverse-engineer branded drugs as the patent applied to the procedure rather than to the active end-molecules (Akhtar, 2013). This had a double impact in the Indian patent scene; boosting exports from national pharmaceutical firms and reducing the incentive of foreign firms to participate in the country (Akhtar, 2013). The concept aimed at avoiding monopolies, as well as providing fair access to medicines (Ramachandran, 2020). As a matter of fact, the Act of 1970 prohibited patents on products that were deemed useful, such as medicines and food, while expanding the practice of compulsory licensing (Liu & Racherla, 2019).

Around 1990, a wave of liberalization in the country began, which culminated in the country's participation to the *World Trade Organization* (WTO) and signature of the *Trade Related Aspects of Intellectual Property Rights* (TRIPS) in 1995, for which the country needed improved compliance. The introduction of the TRIPS in the Indian scene brought the amendment of process patent to product patent, giving higher incentives to multi-national companies to participate in the industry (Aayush Sood, 2019). From then on and considering amendments brought to the legislation, patents began to be granted for a minimum of 20 years and encompass manufacture, use, sale, distribution, importation, and exportation (Mishra & Tiwari, 2020). This increased competition between firms since reverse-engineering patented drugs lost its legality. However, drugs patented before 1995 were still allowed to be generically produced, which maintained the profitability for generic exports (Liu & Racherla, 2019). Through these developments the influence of the TRIPS had become noticeable in the market.

The re-introduction of product patents was feared to have negative effects in the industry, though no evidence substantiates this (Horner, 2019). In fact, the spending in R&D among branded generics increased after the adoption of this measure, and developed forward from rather simple "reverse-engineering" processes. Domestic firms however, were deemed to be still behind when producing *original* drugs, as their R&D focused on the development of generic drugs, even while representing the majority of industry players (Shah, 2019). Despite this new age of liberalization, the amendments to the Indian legislation of patents remained true to their core values. It was determined that no new policy should adversely affect affordable and accessible medicine, and that any abuse from multi-national companies should be prevented (Liu & Racherla, 2019). Affordability remained important to the Indian government, which is why policies were implemented aiming at controlling prices of innovator drugs from multinational firms and supporting generic production (Aayush Sood, 2019). The country was not new to the control of pricing in pharmaceuticals, the New Drug Policy of 1978, as well as subsequent control mechanisms and policies, ensured controlled prices of essential drugs (Horner, 2019). These control policies have always been regarded skeptically, some consider they hindered opportunities in the private sector (Horner, 2019). By 1995, just 74 drugs had their priced controlled in the country, and since then public organizations have argued that more control was needed (Horner, 2019). The number of controlled prices, including generic and patented drug,s has since continuously increased to 929 controlled formulations in 2015, following the *National List of Essential Medicines*. Civil society groups consider the number to be low, while branded multi-national companies believe they negatively affect the industry (Horner, 2019). Keeping the view on price caps as ways to regulate branded pharmaceutical manufacturers is nonetheless limiting. The country's policy keeps the generic pharmaceutical industry in consideration when meeting social goals. Notwithstanding, it strives to provide an ecosystem for innovation through the use of common production facilities available to all types of domestic pharmaceutical firms (Liu & Racherla, 2019).

As of today, India seeks a major transformation of its pharmaceutical industry heading in the direction of cutting-edge innovator drugs (Dandekar, 2024). This strategy proves difficult, as the global innovative pharmaceutical market is dominated by western firms in the likes of Pfizer and Novartis (Dandekar, 2024). The Department of Pharmaceuticals (DoP) is the main governmental authority in the industry and as of September of 2023 launched the Scheme

for Promotion of Research and Innovation in the Pharma-MedTech Sector (PRIP) covering a period of five years (ANI, 2023). The scheme aims at promoting drug discovery, novel drug delivery systems, evaluation of drugs for repurposing, and boosting core technologies shifting the industry from a cost-based to an innovation-based focus (ANI, 2023).

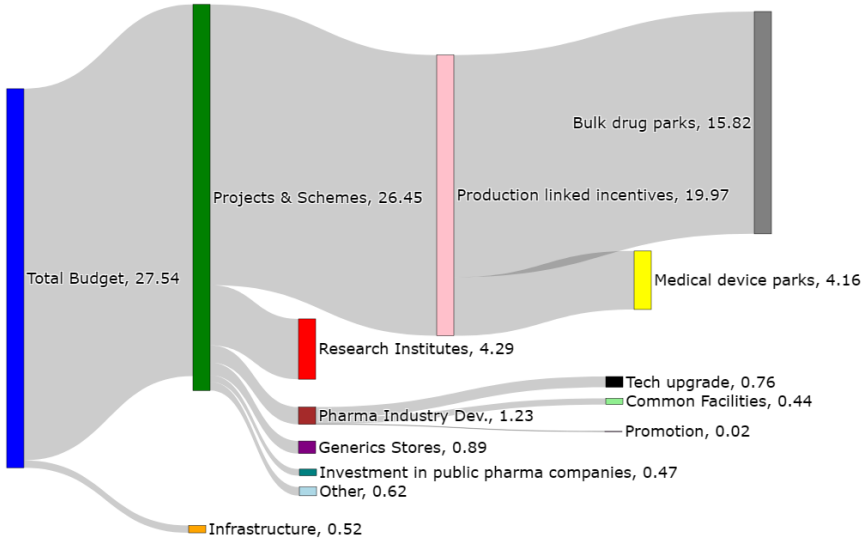


Figure 1: India's department of pharmaceuticals budget decomposition, 2023

The willingness to modernize the industry can be observed through investments in industry-academia programs, research institutes, and even direct investments in public pharmaceutical companies. Generic firms, be it branded or pure generics, also benefit from the large investments of India's department of pharmaceuticals. As depicted in Fig. 1, the majority of the budget is directed towards production-linked incentives (DoP, 2023), benefiting branded and non-branded firms through investments in infrastructure for bulk drug parks reducing production costs. Investing in bulk drug parks and other public infrastructure is a way for Indian companies to become self-reliant and match global industry standards (ILO Consulting, 2020). It also aims at attracting national and foreign companies, who are reluctant of establishing innovative R&D investments in the country. Production-linked incentives are directed to all pharmaceutical firms, and they are expected to "promote innovation for development of complex and high-tech products" which includes "products of emerging therapies" (Press Information Bureau of India, 2021). This hints at the willingness of the government to diversify the industry towards innovative R&D instead of remaining generic-focused. The budget also includes a general promotion scheme to call for external investments benefiting the pharmaceutical industry.

Pharmaceutical firms benefit from these investments, which help them achieve production costs that are comparable between them. However, investments towards R&D are not as predominant as production incentives, which implies any schemes aiming to promote innovative

R&D among national firms might need to be conducted through additional institutions or initiatives. Decomposing the budget of the DoP points to some lack of direct investments in the innovative-to-be firms which can possibly result in a misalignment of incentives. In this sense, practices that are usually in place in the Indian scene involve wrongfully signalling innovation-linked investments, as new inventions through product-hopping or evergreening. Evergreening is a general term referring to the exploitation of loopholes by a patent holder to keep the monopoly over best-seller or maintain profit sources from sold drugs marketed as "new inventions" by applying for patents over "disguised", previously-patented inventions (N. Kumar, 2003). In the pharmaceutical industry, evergreening can be defined as the filing of a new patent over minor, non-imperative, changes of an already-existing molecule. This practice is well established among innovative pharmaceutical products in India.

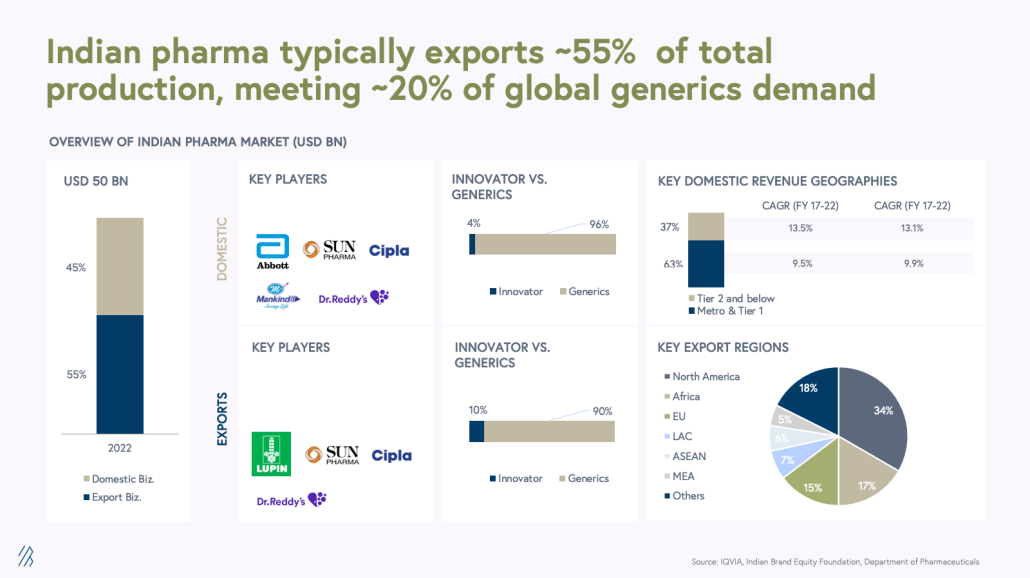
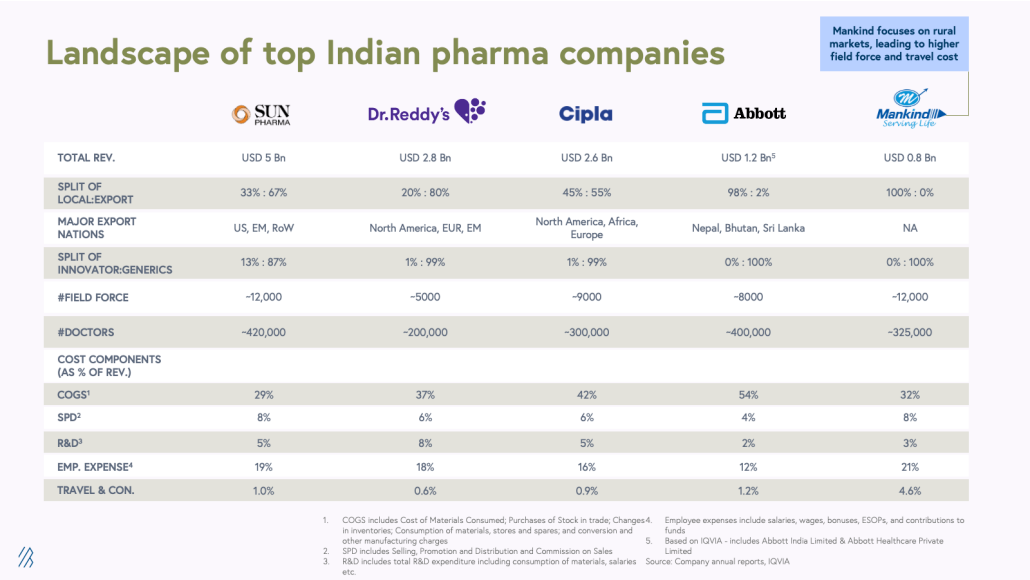


Figure 2: Key market players and figures of the Indian pharmaceutical industry
Source: Matican, 2023

Today the industry is characterized by long-established branded generics as key players. The country benefits from a large share of exports as seen in Figure 2. Despite this incentive programs the market is still dominated by the production of generics. Only 4% of the domestic drug sales volume is covered by innovator drugs. Among exported drugs, the share of innovator drugs merely reaches 10%. These branded generics have grown and benefited from the historical events described above to develop their infrastructure and their soft and hard capital. As shown in Figure 3, only three of the five largest branded generics firms in India venture in the production of innovative R&D, namely SUN Pharma, Dr. Reddy's, and Cipla. The share of innovator drugs in their portfolio is almost negligible for the latter two, the largest share being that of SUN Pharma with 13% innovator products and a total R&D expenditure of 5% their total revenue. The largest spending in R&D is however attributed to Dr. Reddy's at 8%. SUN Pharma is the reference firm when it comes to the new wave of innovation in India, with the company expanding its pipeline of innovative drugs into the US as well (Dandekar, 2024). This willingness to innovate is what the schemes organized by the Indian government aim to optimize through the department of pharmaceuticals, and more specifically production linked incentives.



Landscape of top Indian pharma companies

Mankind focuses on rural markets, leading to higher field force and travel cost

	SUN PHARMA	Dr.Reddy's	Cipla	Abbott	Mankind Serving Life
TOTAL REV.	USD 5 Bn	USD 2.8 Bn	USD 2.6 Bn	USD 1.2 Bn[5]	USD 0.8 Bn
SPLIT OF LOCAL:EXPORT	33% : 67%	20% : 80%	45% : 55%	98% : 2%	100% : 0%
MAJOR EXPORT NATIONS	US, EM, RoW	North America, EUR, EM	North America, Africa, Europe	Nepal, Bhutan, Sri Lanka	NA
SPLIT OF INNOVATOR:GENERICS	13% : 87%	1% : 99%	1% : 99%	0% : 100%	0% : 100%
#FIELD FORCE	~12,000	~5000	~9000	~8000	~12,000
#DOCTORS	~420,000	~200,000	~300,000	~400,000	~325,000
COST COMPONENTS (AS % OF REV.)					
COGS[1]	29%	37%	42%	54%	32%
SPD[2]	8%	6%	6%	4%	8%
R&D[3]	5%	8%	5%	2%	3%
EMP. EXPENSE[4]	19%	18%	16%	12%	21%
TRAVEL & CON.	1.0%	0.6%	0.9%	1.2%	4.6%

1. COGS includes Cost of Materials Consumed; Purchases of Stock in trade; Changes in inventories; Consumption of materials, stores and spares; and conversion and other manufacturing charges
2. SPD includes Selling, Promotion and Distribution and Commission on Sales
3. R&D includes total R&D expenditure including consumption of materials, salaries etc.
4. Employee expenses include salaries, wages, bonuses, ESOPs, and contributions to funds
5. Based on IQVIA - includes Abbott India Limited & Abbott Healthcare Private Limited

Source: Company annual reports, IQVIA

Figure 3: Decomposition of top branded generics' activities
Source: Matican, 2023

4.2 Key dynamics in the industry: compulsory licensing and evergreening

Kumar and Nanda (2017) mention some examples of practices by branded firms to protect existing patents with evergreening:

1. Combining two or more existing drugs and market it as a new drug.
2. Varying dosage, delivery profiles, or mechanisms of actions.
3. Use of isomeric forms or derivatives of an already-existing drug.
4. Different packaging or methods of treatment.

Evergreening remains an issue largely attributed to purely innovator pharmaceutical firms, but if R&D is to be developed in the country as the Indian government seeks to, evergreening must be considered when designing new policies. The practice of introducing this type of patents, which in this thesis are referred as secondary patents, is not necessary illegal as long as the intention behind it is clearly stated. Requesting a complementary or secondary patent can be aimed at improving the stability of a molecule, reduce its side effects, or optimize manufacturing processes. This transparency regarding secondary patents has already been observed and is different from evergreening. Evergreening in this context refers to signalling what would be a secondary patent as primary. For instance, a patent request from the branded generics firm Teva Pharmaceutical Industries Ltd. filed in 2005 aimed at stabilizing the pharmaceutical composition of an acid labile drug (Teva Pharmaceuticals Ltd. *et al.*, 2006). Innovation over already-existing drugs is possible, but should be depicted as secondary. The patent should be filed over the modifications and not the already-patented active molecules. When branded firms file patents over "new inventions" that in reality are simple modifications of existing drugs, the true objective is the company's economic advantage (Collier, 2013).

4.2.1 The case of Gleevec: Novartis vs. the Indian government

Due to the extensity of classic generic producers' market share, there has been a strong lobby against exclusivity of data within the pharmaceutical industry, i.e. patents. In the year 2006, a patent request for a beta crystalline form of the drug *imatinib mesylate*, intended as a treatment for leukaemia, was introduced in India under the name Gleevec. The Madras Patent Office rejected the patent, arguing that *imatinib mesylate* was already known and the compound in question was simply a derivative (A. Kumar & Arun, 2017). The decision was appealed to the Intellectual Property Appellate Board which modified the decision, though the rejection was upheld due to the lack of novelty of the core compound. The litigation escalated to the Supreme Court, where Novartis argued "enhanced efficacy" of the "new" compound and that the decision went against the TRIPS agreement (Liu & Racherla, 2019). The Supreme Court recognized the possible novelty but further upheld that no valid claims on "enhanced efficacy" were applicable (A. Kumar & Arun, 2017). Simultaneously, the High Court also ruled that India had a constitutional duty to provide proper healthcare, being a welfare country with a large population living below the poverty line, which was reinforced by the Supreme Court (Liu & Racherla, 2019). India also made use of some flexibilities within the TRIPS agreement to reject this patent, though this enters a scope beyond that of this research.

The Novartis case provides interesting insights as to what the consequences for the drug price were. After the patent was rejected, generic production was launched and the selling price of *imatinib mesylate* went from *Rs.* 4115 per tablet to *Rs.* 30 per tablet, or from US$ 50.45 per tablet to just US$ 0.37 per tablet, translating to a 99% reduction in selling price. Considering a daily consumption of one tablet per day, this translates in a treatment cost reduction from US$ 18.414,21 per year to just US$ 134,25. The firm that obtained production approval through compulsory licensing was SUN Pharma, the largest branded generics firm in India. Thereafter, production had no limitations quantity-wise and both availability and affordability were guaranteed across the country. As to Novartis, it became impossible to compete against such low prices in the country and had to desist. The case of Gleevec gives insights into how drug prices differ between patent-protected products and generic production. It also shows that compulsory licensing is a powerful tool to control the market as companies find it impossible to compete against generic prices. The decision was applicable in the complete territory of India which is why Novartis lost the market share over the whole territory and halted production of the drug in India.

4.2.2 Debating the efficiency of compulsory licensing to deal with evergreening

Branded firms producing innovative drugs practice evergreening since the development phase of drugs is highly costly both monetarily and timewise. It takes between 10 to 15 years to bring a new drug into the market, with around US $1 billion in R&D investments and a 90% probability of failure (Sun, 2022). These figures depict the general landscape of high-end R&D in pharmaceuticals, independently of the country. This high risk characteristic of the pharmaceutical firm is mostly due to the drug not producing its intended effect in patients during trials, toxicity or adverse side-effects, or poor absorption and excretion (Sun, 2022). Moreover, evergreening represents a consequence of a vicious cycle, innovative firms tend to practice it since generic drugs would impede them to attract a market share (A. Kumar & Arun, 2017). The problem of evergreening if innovation is to flourish in India is even more considerable. Branded generics represent the largest players in the industry with 75% of the

market in volume, 90% in value; these firms' resources allowed them to start venturing in the production of innovative drugs while remaining active in the global supply of generics (Bohra, 2023. As a reference, India's global market share in pharmaceuticals is around 13% in volume total, and its global market share for generic pharmaceuticals is 20% (Aggarwal, 2023).

As of today, India's main economic driver for its pharmaceutical industry remains generic drug production, which implies the need of incentives to foster original innovation (Shah, 2019). Evergreening thus characterizes a blockage to innovation while worsening unaffordability. To control it, the Indian government opted for compulsory licensing (Liu & Racherla, 2019). Compulsory licensing is defined as the authorization for a third party to make, use or commercialize a patented product without necessarily having the consent of the patent owner (Grace *et al.*, 2003). Compulsory licensing has historically been applied to drugs from multinational companies, but remains the main tool to shift production to low-cost drugs. Whenever an Indian generic manufacturer sees a request for voluntary license rejected by a branded manufacturer, they can launch a counter-request for compulsory licensing; if said patent is granted to the generic manufacturer, the patent holder will receive 6% of total profits as per the TRIPS agreement (Gandhi, 2019). On a more general ground, Gandhi (2019) explains that compulsory licenses can be granted after the expiration of a period of three years after the grant of the patent. Compulsory licenses represent a method of brute force to solve the problems of unavailability and unaffordability. The standard reasons presented in the Patent Act for compulsory licensing are whether the drug was unavailable (meaning the public was not satisfied), or unreasonably priced (as per the perspective of the public), or simply not supplied properly. Compulsory licensing is different from patent refusal, for which there can be several reasons that revolve around the legality of the patent, *e.g.* the use of unauthorized molecules, or filing so-called obvious patents (Khanna, 2023).

Evergreening, however illegal, is not considered as a standard to grant a compulsory license, since it does not necessarily imply unavailability, unaffordability, or improper supply. Compulsory licenses have nonetheless been used to stop evergreening. In this sense, it can be understood that India has tried to balance innovation with drug affordability and availability after joining the WTO, though prior large presence of generic producers in the industry has led the country to find a middle-ground which, for now, resides in compulsory licensing. This can be debated, and the use of compulsory licensing as primary tool against evergreening can be questioned. An independent report demonstrated that the majority of patents granted for pharmaceuticals in India consist in marginal improvements over already-existing parent molecules (Jishnu, 2018). Out of 2.293 patents from 2009 to 2016, which included patent requests from purely innovative firms as well as from firms typically considered branded generic manufacturers, around 72% of patents could be considered as simple secondary patents and not new inventions. As shown in Figure 2, only 15% of patents were subject to proper scrutiny (Jishnu, 2018). The reasons for this unproper verification of patents are argued to be various; lack of human resources, laxity from authorities, or even flexibility towards "innovative" firms. This supposed flexibility to evergreening might have as root-cause the low investments and support in R&D coming from the government. Due to generics production being the main industry strengths, India invests around 0.7% of its GDP in innovative R&D, while other countries with similarly valued pharmaceutical industries invest around 3% (P. Sharma, 2023). To develop innovative R&D by leveraging the established pharmaceutical industry

and ensuring availability and affordability, the country needs to implement further schemes in order to make sure investments are not being misdirected. It can be understood that this is, in a way, a Principal-Agent incentive conflict. In the case where the government would agree to finance part of the R&D investments, it acts in a setup of asymmetric information, not knowing whether the drug will be characterized as "highly" or "poorly" innovative. Hence, it must be studied whether the government gains or loses from implementing higher scrutiny against evergreening, or from remaining in a context of hidden patent information.

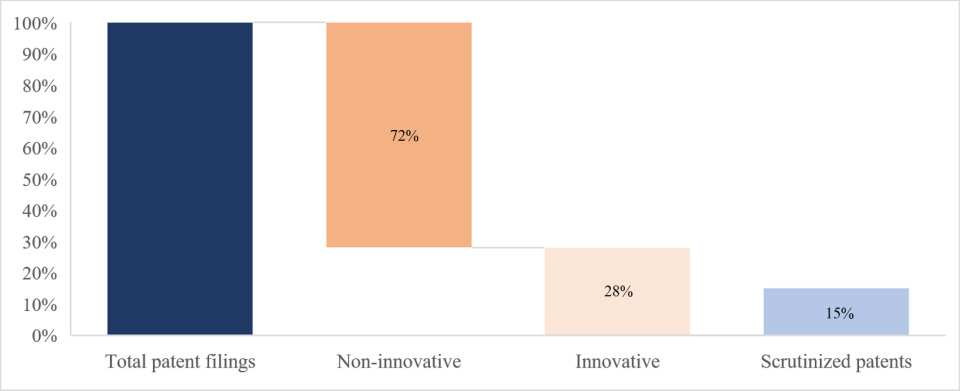


Figure 4: Decomposition of patent filings by innovation and scrutiny
Source data: Jishnu, 2018

Other legal grounds allow compulsory licensees to export produced drugs to countries in need. Some also allow generic producers to experiment with biosimilars in order to prepare the production process for when the patent expires. However, these measures are not considered in this thesis since they are mainly based on legal aspects and affect the time period after the patent comes into expiration. A scheme that allows a branded firm to recover R&D costs during the patent life while ensuring availability and affordability is the main conflict to be resolved.

4.3 The Indian pharmaceutical market

The global pharmaceutical industry is described as being highly research intensive. As a reference, innovative firms spent around 15% of sales turnover for R&D expenditures. In the case of India during the 2000s, this figure remained at a very low 2% of sales turnover dedicated to R&D as it is depicted in Figure 5. The reasons for such low investments are attributed to the production of generic drugs and the avoidance of cost-intensive R&D activities by most of the industry (Reji, 2011). This trend was increasing and remained so in the last decade. As of 2023, this figure stands at less than 13% on average (Statista, 2023).

Today, India still faces an important lack of innovative drugs production. The industry still bets on generics as the main source of revenue. Among the participant firms, 87% of generic manufacturers are "branded generics" (Competition Commission of India, 2021). These firms have become large corporations and are resourceful in infrastructure, scientific capital, and production capabilities. Their soft- and hard-capital is firmly established and could allow them to venture into innovative R&D. Nonetheless, many of them prefer not to. The phenomenon is almost unique to India; the core business of these firms is generic production.

This generic production does not come as white-label solutions but rather products attached to a brand (Competition Commission of India, 2021). In these market conditions, Indian pharmaceutical companies prefer to avoid venturing in innovative R&D since the market and the demand are more adapted for generics. This stresses the importance to promote innovation on the government's side. Moreover, R&D is a part of branded generics activities though not in the same scale, risk, or purpose as classic innovative firms. Innovative firms develop active molecules from start to finish while testing the success of it, which comes with a high probability of failure. Generic firms do not face the same uncertainty. Such is the case of Teva, a branded generic company with activities in India and Israel. In 2020, the company invested nearly $1 billion on R&D activities with a portfolio of around 1160 generic drugs and around 50 pipeline products (Teva Pharmaceuticals Ltd., 2021). Branded generic firms spend comparable investments in R&D as innovative firms, although they do not share the same risk, since the active molecule is already existent. Hence, if the Indian government is to promote innovation and incentive R&D in the pharmaceutical industry, it must also consider doing so for branded generics that would remain in the generics business. These so-called "branded generics" dominate the domestic industry of India and have begun venturing in the development of innovative pharmaceuticals *i.e.* new active molecules. An example case is Dr. Reddy's Laboratories which produces branded generics and also researches new active molecules (McKinsey, 2022). If India is to leverage its innovative pharmaceutical industry, it would do so through already established branded generics.

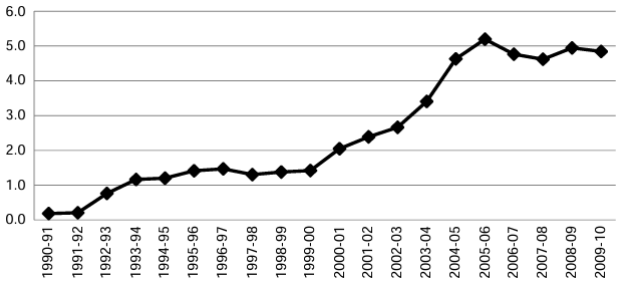
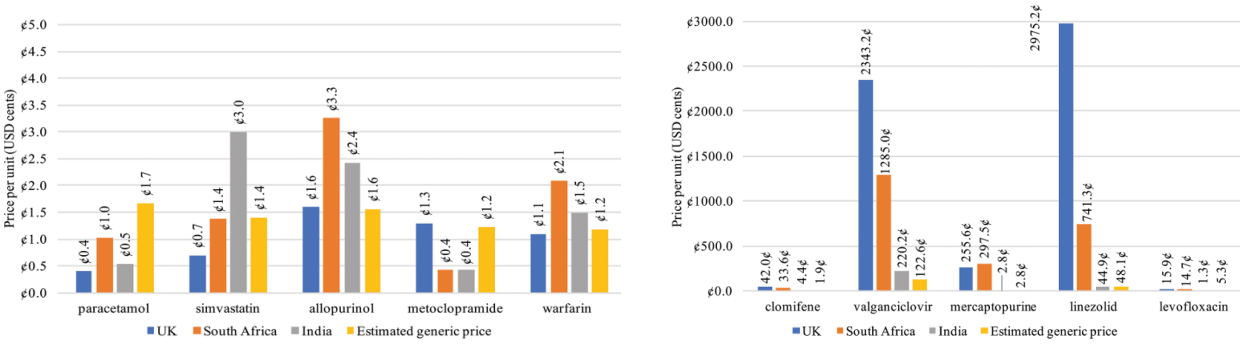


Figure 5: India's R&D-Sales ratio throughout the years.
Source: Reji, 2011

India is characterized by having drug prices commonly cheaper than other countries, even regarding drugs with typically large price variation across countries as seen in Figure 6. Several drug prices are capped in India, showing the willingness of the authorities to directly intervene in pricing as reported by the National Pharmaceuticals Pricing Authority (National Pharmaceuticals Pricing Authority, 2022). The authority also reports ongoing litigation cases of overcharging that date back to 1979 and involve major global firms. A study by Hill *et al.* (2018) focused on predicting price variability for medicines in India and their benchmark with other countries, along with an estimation of the generic price version. This is a consequence of the resources and specialization the Indian industry received through engineering and producing generic drugs. Patented drugs also have cheaper prices in comparison to prices abroad, but are less affordable than in countries as China or Brazil due to poor health coverage and insufficient financial support from the government (Y. S. Sharma & Das, 2014). Prices for branded generics can be highly dependent on the type and purpose of the drug, and their value abroad can significantly differ than the domestic price. This further incentives the majority of branded generics to remain in classic generic manufacturing.



((a)) Low variations ((b)) High variations

Figure 6: Example prices of medicines from branded generics with low and high variations in prices.
Source: Hill *et al.*, 2018

The expenditure in medicines by Indian citizens is characterized by being 78% out-of-pocket. Out of this expenditure, only 0.9% is estimated to be on patented drugs despite prices being 27% the rate proposed in developed countries on average (Y. S. Sharma & Das, 2014). Production and sales data medicine-specific for India is hard to come by, and is often specific to the type and purpose of the drug. Official reports on sales volume of medicines are available, but the data is valid for all pharmaceuticals without discriminating between patented and generic. Table 1 exhibits the total sales value and volume for the 10 largest segments of medicines out of 20. These numbers can be interpreted along with the previously mentioned market statistics to show the current state of low innovative R&D sales in India.

Table 1: Sales value and volume for largest segments of medicines, India, July 2020
Source data: Competition Commission of India, 2021

THERAPY	**VALUE**			**VOLUME**	
AREA	Millions $US		In Percent	In SUs	In Percent
CARDIAC	$	231.24	13%	33,739	17%
ANTI-INFECTIVES	$	229.75	13%	13,152	7%
GASTRO INTESTINAL	$	190.81	11%	32,051	16%
ANTI DIABETIC	$	175.85	10%	17,313	9%
VITAMINS / MINERALS /NUTRIENTS	$	149.12	9%	17,227	9%
RESPIRATORY	$	134.77	8%	16,247	8%
PAIN / ANALGESICS	$	115.47	7%	19,035	10%
NEURO / CNS	$	106.76	6%	15,583	8%
HORMONES	$	32.34	2%	17,835	9%
Total Market	$	1,728.49	**100%**	196,242	**100%**

5 Model

The interaction between a government and a branded firm can be modelled reflecting a buyer and seller relation. Through the use of coordination contracts studied in the literature review, optimal quantities that maximize the social surplus can be achieved. It is the government that aims at maximizing the social surplus its population obtains when drugs are sold. In such sense, the interaction is modeled here as a buyer that gets a per unit benefit r^i, also considered as a marginal societal benefit per sold unit. This marginal societal benefit can be estimated through econometric analysis as a return on R&D or on sold units obtained by the government. Valuing the benefit brought by pharmaceuticals has also been conducted in research regarding value-based pricing of pharmaceuticals. The methods can be used to estimate the social surplus pharmaceuticals bring enabling a pricing that benefits patients, innovation, and health systems (EFPIA, 2023). However, estimating these returns is beyond the topic of the model since it encompasses a model by its own which estimates a monetary social return per unit. Nonetheless, the concept of social return for pharmaceuticals can also be applied which estimates a return on a products R&D and selling prices (Pekarsky, 2014, S. Wu & Lindgren, 1984).

Innovation incentives from the Indian government have consisted mainly in common infrastructure through production-linked incentives plans. These investments were designed to boost innovator R&D, though the current state of the market has demonstrated that the industry continues to rely on the production of generic drugs. Thus, the government needs a mechanism to encourage and coordinate innovation among pharmaceutical firms. When doing so, the government should also consider the non-innovative R&D necessary for the production of generics as well as truthful secondary patents. Similarly, it should account for firms that miscommunicate their innovation quality through evergreening or untruthful secondary patents. The branded firm acts as the seller which could provide an innovative product of two types $i \in \{H; L\}$. H stands for high innovation while L stands for low innovation. High innovation is considered here as the development of new active molecules, which are more valuable since they have the possibility to tackle diseases or conditions that have yet to receive a treatment, thus $r^H > r^L$. This is the innovation that India expects to promote through their incentives towards the pharmaceutical industry. Low innovation in this context relates to a branded generic firm's traditional spending on R&D, truthful-, and untruthfully-signalled secondary patents. More specifically, low innovation can be defined as R&D spending for better stability of the drug, fewer side-effects, and/or simpler production processes, though it has no intrinsic uncertainty as the development of new molecules in high-end R&D. In fact, R&D spending in type L is considered here as certain; success is guaranteed as the active molecules already exist and the production process must simply be developed. If R&D costs are to be shared with public spending, then the government might or might not conduct appropriate screening to identify the innovation type it seeks to promote.

On the basis that the government provides production-linked incentives, as it was shown in the India case study with common bulk drug parks among other types of infrastructure, the model considers a common marginal production cost c_p for both types of manufacturers independent of the type of innovation. This can also be argued by the fact that firms entering innovative R&D of type H would be already-established branded generics with developed production infrastructure

being used for both innovative and generic drugs. This also aligns with the observations in the case study, which hinted at disparities in R&D costs between firms and/or projects as the source for price disparities. The coordination scheme in this work is based on research of Cachon (2003) and Linqiu (2021) who developed capacity procurement contracts, cost-sharing mechanisms introduced by Koo (2022) and Jian (2023), as well as contract theory presented by Bolton (2004), and contracting under asymmetric information researched by Schmitz (2021). The R&D phase enables production of the drug up to a certain quantity or capacity. R&D not only determines the end-product, with its certain degree of innovation, but also production processes, thus defining throughput and quantity (Teva Pharmaceuticals Ltd., 2021). In this sense, innovation is translated through a build-up of capacity during the R&D phase namely R^i which comes at a per unit R&D cost of c_R^i where $c_R^H > c_R^L > c_p$. The built capacity is based on a forecast x^i shared by the government, which the firm uses in order to determine R^i. Developing new active molecules comes with high risk of failure as well with a higher marginal societal benefit. In this sense, the expectation for the probability of success in the R&D phase is defined as $P(Y = 1) = \gamma$ while failure becomes $P(Y = 0) = 1-\gamma$. This variability is however not present on innovation type L, as they do not involve developing new active molecules. The choice of the appropriate coordination mechanism is based on the models by Linqiu (2021), Koo (2022), and Jian (2023) and is defined as a linear R&D cost-sharing ψ^i for the per unit R&D cost c_R^i. The consideration of hidden information is inspired by the research of Bolton (2004) and Schmitz (2021).

Table 2: Summary of notations

Notation	Definition
x^i	Forecast provided by the government for type $i \in \{H; L\}$
r^i	Marginal societal return of innovative drug type $i \in \{H; L\}$
p^i	Unit price of drug type $i \in \{H; L\}$
c_R^i	Marginal cost of R&D for type $i \in \{H; L\}$
c_p	Marginal cost of production
R^i	R&D capacity built by type $i \in \{H; L\}$
ψ^i	R&D cost-sharing parameter for type $i \in \{H; L\}$

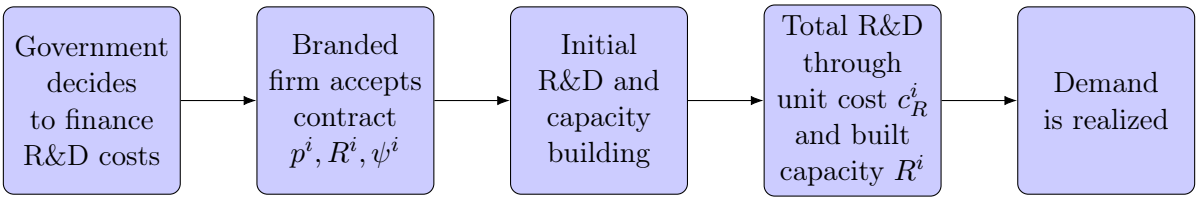


Figure 7: Sequence of events

5.1 R&D coordination through investment cost-sharing

Building up capacity throughout the R&D phase involves several costs which are summarized through the unit R&D cost parameter c_R^i. Initially, all the information needed to determine the R&D capacity is considered as observable and verifiable by all parties in the business relation. More specifically, it is assumed that demand information is symmetrical. This is because this work's India case study demonstrated the prevalence and dominance of branded generic firms

over the domestic market implying these firms conduct and base their production capacities using their own forecast and market knowledge. It is hence assumed, that the government earns nothing in over-estimating the domestic demand forecast since ultimately it can expect it to be conducted by the firm. Similarly, the firm earns nothing in over- or under-estimating the forecast of the government since it has firsthand access to demand- and market-data. However, this might not be the case in crisis scenarios such as a pandemic, where demand information asymmetry is more compelling. Moreover, the model is tailored for cases where it is the pharmaceutical firm conducting the sales and distribution, as it was the case for multinationals like Novartis or branded generics like Teva. This is opposed to the traditional manufacturer-supplier relation typically considered in capacity procurement games, where the downstream member is in charge of selling the end-product. The built capacity through R&D investments thus defines the production as $Q^i = min\{x; R^i\}$. This is further refined into expected sales:

$$S(R^i) = R^i - \int_0^R F(x)\,dx$$

Decisions can then be coordinated between government and firms to achieve service levels when conducting innovative R&D.

5.1.1 Benchmark model, a centralized scheme

The centralized scheme, can also be used to describe nationalization since it represents a single entity's optimization, yields the optimal production quantities for each innovation type determined through the separate optimization programs for types H and L. In this scenario the manufacturer is a state company developing and manufacturing drugs and has complete control over the type of innovation to develop. Proof for type L can be found in the annexes.

Lemma 1 *The optimal capacities built through the R&D phase in a centralized coordination contract for types H and L are given by:*

$$R_C^{H^o} = F^{-1}\left(1 - \frac{c_R^H}{\gamma \cdot (r^H - c_p)}\right) \tag{1}$$

$$R_C^{L^o} = F^{-1}\left(1 - \frac{c_R^L}{(r^L - c_p)}\right) \tag{2}$$

Proof for type H: The objective function with upper-script C for "Centralized" is given by the following profit and expected profit functions:

$$\max_{R^H} \Pi_C^H = P(Y=1) \cdot \left[(r^H - c_p) \cdot \min\{x^H, R^H\} - c_R^H \cdot R^H\right] + P(Y=0) \cdot \left[-c_R^H \cdot R^H\right]$$

$$\max_{R^H} E\left[\Pi_C^H\right] = \gamma \cdot \left[(r^H - c_p) \cdot S(R^H) - c_R^H \cdot R^H\right] + (1-\gamma) \cdot \left[-c_R^H \cdot R^H\right]$$

The expected profit function yields the FOC exhibited here below. By isolating the R&D capacity build-up the result above mentioned can be found:

$$\frac{dE\left[\Pi_C^H\right]}{dR^H} = \gamma \cdot (r^H - c_p) \cdot (1 - F(R^H)) - c_R^H = 0$$

Both of these optima quantities are defined over a critical ratio between the marginal R&D investment cost c_R^i and the spread between marginal societal benefit r^i and production cost

c_p. Coordinated decisions between the government and the firms cannot be achieved if no contractual mechanism is in place. As firms maximize their expected profits, the built-up capacity in R&D phases will differ, affecting final production quantities and prices.

Corollary of Lemma 1 *In a decentralized setting where there is no R&D coordination through government-based cost-sharing mechanisms, unit drug prices hinder welfare by surpassing unit marginal social benefits:* $r_i \leq p_i$

Proof for type H: The objective function with upper-script D for "Decentralized" is given by the following profit and expected profit functions:

$$\max_{R^H} E\left[\Pi_D^H\right] = \gamma \cdot \left[(p^H - c_p) \cdot S(R^H) - c_R^H \cdot R^H\right] + (1-\gamma) \cdot \left[-c_R^H \cdot R^H\right]$$

Deriving the FOC of this last equation and isolating the build-up of capacity through R&D yields the following result:

$$R_D^{H^*} = F^{-1}\left(1 - \frac{c_R^H}{\gamma \cdot (p^H - c_p)}\right)$$

Considering the results obtained in *Lemma 1*, in order for $R_{D;FI}^{H^*}$ to be greater or equal to $R_{D;FI}^{H^o}$, it would be necessary that $\frac{c_R^H}{\gamma \cdot (p^H - c_p)}) \leq \frac{c_R^H}{\gamma \cdot (r^H - c_p)}$ which implies that $r_H \leq p_H$.

The corollary on *Lemma 1* suggests that the marginal societal benefit of the drug is lower than the price. Hence, in a decentralized setting, even with full information on the type of innovation, the drug negatively affects welfare due to high prices. The same reasoning can be applied to secondary patents with the same conclusion being obtained, optimal decentralized production quantities are too expensive for the final consumers. Hence, in the case where the government does not offer R&D support to firms, the social benefit is hindered.

5.1.2 Coordination through R&D cost-sharing under innovation discrimination

This section will demonstrate how coordination can be achieved when the government can screen each patent request individually without recurring to nationalization. When R&D investments are shared with the government, the firm would only have to cover the fraction $(1-\psi)$ of these. The focus is on innovation type H as results for type L are analogous.

Lemma 2 *The R&D cost-sharing contract is defined through a given combination of price and cost-sharing ratio* $\{p^i; \psi^i\}$ *can be defined through the following relation, valid for both types of innovation i:*

$$\psi_{CS;FI}^i = 1 - \frac{p_{CS;FI}^i - c_p}{r^i - c_p}$$

The price in turn, is found by rearranging the previous equation and is equal to:
$p_{CS;FI}^i = (1 - \psi^i) \cdot (r^i - c_p) + c_p$

Proof: The firm type H maximizes its expected profit through the convex profit function illustrated in equation (3). Solving the FOC in (4) results in the optimal R&D-built capacity exhibited in equation (5).

$$\max_{R^H} E\left[\Pi_{CS;FI}^H\right] = \gamma \cdot \left[(p^H - c_p) \cdot S(R^H) - (1-\psi^H) \cdot c_R^H \cdot R^H\right] + (1-\gamma) \cdot \left[-(1-\psi^H) \cdot c_R^H \cdot R^H\right] \quad (3)$$

$$\frac{dE\left[\Pi^H_{CS;FI}\right]}{dR^H} = \gamma \cdot (r^H - c_p) \cdot (1 - F(R^H)) - (1 - \psi^H) \cdot c^H_R = 0 \tag{4}$$

$$R^{H^*}_{CS;FI} = F^{-1}\left(1 - \frac{(1 - \psi^H) \cdot c^H_R}{\gamma \cdot (p^H - c_p)}\right) \tag{5}$$

The optimum R&D-built capacities and prices obtained through centralization can only be achieved if $\frac{(1-\psi^H)\cdot c^H_R}{\gamma\cdot(p^H-c_p)}) = \frac{c^H_R}{\gamma\cdot(r^H-c_p)}$. This last equation allows to define the unit price $p^i_{CS;FI}$ that achieves coordination while remaining lower than the marginal societal benefit. The government in turn, maximizes it's expected societal surplus through equation (6) and considers the share of R&D costs to share with the branded firm.

$$\max_{R^H} E\left[\Pi^G_{CS;FI}\right] = \gamma \cdot \left[(r^H - p^H) \cdot S(R^H) - \psi^H \cdot c^H_R \cdot R^H\right] + (1 - \gamma) \cdot \left[-\psi^H \cdot c^H_R \cdot R^H\right] \tag{6}$$

The FOC of this last equation defines $F(R^H_{CS;FI;G}) = 1 - \frac{\psi^H \cdot c^H_R}{\gamma\cdot(r^H - p^H)}$ and $R^H_{CS;FI;G} = F^{-1}(1 - \frac{\psi^H \cdot c^H_R}{\gamma\cdot(r^H - p^H)})$. Equating the ratio of this result to $\frac{c^H_R}{\gamma\cdot(r^H - c_p)}$ defines $p^H_{CS;FI;G}$ through equation (7).

$$p^H_{CS;FI;G} = r^H - \psi^H \cdot r^H + \psi \cdot c_p + (-c_p + c_p) \tag{7}$$

Rearranging equation (7) yields the same result obtained in the corollary of *Lemma 1* and thus coordination is achieved. The results for type L are analogous: $R^{L^*}_{CS;FI} = F^{-1}(1 - \frac{(1-\psi^L)\cdot c^L_R}{(p^L - c_p)})$ for the pharmaceutical firm, and $R^{L^*}_{CS;FI;G} = F^{-1}(1 - \frac{\psi^L \cdot c^L_R}{(r^L - p^L)})$ for the government. Equating the ratios to the critical ratio $\frac{c^L_R}{(r^L - c_p)}$ yields in both cases a definition for p^L_{CS} as per equation (8).

$$p^L_{CS;FI} = (1 - \psi^L) \cdot (r^L - c_p) + c_p \tag{8}$$

By rearranging equations (7) and (8) the definition of the cost-sharing ratio can be displayed. For both types of patents the share of R&D costs is defined as exemplified in relation (9) and is independent on development uncertainty.

$$\psi^i_{CS;FI} = 1 - \frac{p^i_{CS;FI} - c_p}{r^i - c_p} \tag{9}$$

Drug price and cost-sharing ratios are determined by the government by considering what configuration maximizes total surplus. It can also be the case, that the firm can bargain when determining the final contract parameters based on its market share or R&D infrastructure. In any case, coordination is achieved through sharing R&D investments. The branded firm builds the necessary capacity through expensive R&D investments shared by the government and the price does not hinder the societal benefit. For both types of innovation, when the government takes on the responsibility of financing all R&D-related costs ($\psi = 1$), the selling price of the drugs will drop to the cost of production c_p. This can be considered as the case where pharmaceutical companies are dependent on the government and R&D is fully funded by the government. However, this scenario is not realistic as it does not guarantee innovation since prices are pushed to marginal costs. A middle-ground for ψ better describes the real world. In addition, pharmaceutical companies have critical human-, technological-, and knowledge-capital that enables the development of new active molecules. Shifting towards a setting where these companies would be nationalized is thus unrealistic. What this model achieves nonetheless, is availability and affordability through optimal build-up through R&D and prices that help maximize the social surplus obtained by the government.

What this work's case study on India showed however, is that the government observes the type of patent, but does not necessarily verify if the patent is deserving of receiving the remuneration and financing.

5.2 R&D cost-sharing in a context of hidden information

The buyer-seller relation between a government and a branded firm can additionally describe the case where the government cannot pre-contractually verify the type of innovation without facing high effort costs. In such a case, the government faces a pre-contractual information asymmetry problem. As it was depicted in the India case, the respective authorities receive several pharmaceutical patent requests which can either be of high- or low-innovation, i.e. are of types $i \in \{H; L\}$. The reason why high-innovation patents are hard to come across might not only be related to costs, but also to incentives. By not being certain of how valuable the innovation of patent request is, the government might offer too low incentives for patents type H. This in turn would lead to a problem of adverse selection where costly high-innovation patents are driven out of the market. Hence, it would explain why generics production remains the most prevalent activity in India despite the immense development of its pharmaceutical industry. The government is not able to or does not differentiate the innovation behind the R&D expenditures. This section demonstrates that applying an R&D cost-sharing contract in the context of hidden information is not efficient since to keep incentives aligned, the solution becomes conflicting for innovation.

5.2.1 Solving incentive conflicts

The sequence of events is as follows; at time t=0, the quality of the innovation is determined by the branded firm and can be either of type H or L. Only the branded firm can verify the real nature of the innovation. The laxity or flexibility from the Indian government implies that it faces a pool of patent requests, with a probability ρ that the patent is of high-quality innovation. At t=1, the branded firm submits the patent request with a signal H or L and the government observes it and determines the financial incentive ψ^i as well as the request of capacity to build through R&D R^i. When demand is realized at t=2, the government is able to measure the quality of the innovation by computing the social surplus. This is done post-contractually and after the selling period. Since branded firms can present a signal that does not necessarily align with the real nature of the patent, post-contractual social surplus can differ from expectations.

$$\max_{R^i,\psi^i} \quad E\left[SB\right] = \rho\left[\gamma(r^H - p^H)\cdot S(R^H) - \psi^H \cdot c_R^H \cdot R^H\right] + (1-\rho)\left[(r^L - p^L)\cdot S(R^L) - \psi^L \cdot c_R^L \cdot R^L\right]$$

s.t.

$$\gamma(p^H - c_p)\cdot S(R^H) - (1-\psi^H)\cdot c_R^H \cdot R^H \geq 0 \qquad (PC_H)$$

$$(p^L - c_p)\cdot S(R^L) - (1-\psi^L)\cdot c_R^L \cdot R^L \geq 0 \qquad (PC_L)$$

$$\gamma(p^H - c_p)\cdot S(R^H) - (1-\psi^H)\cdot c_R^H \cdot R^H \geq (p^L - c_p)\cdot S(R^H) - c_R^H \cdot R^H + \psi^L \cdot c_R^L \cdot R^L \qquad (IC_H)$$

$$(p^L - c_p)\cdot S(R^L) - (1-\psi^L)\cdot c_R^L \cdot R^L \geq (p^H - c_p)\cdot S(R^L) - c_R^L \cdot R^L + \psi^H \cdot c_R^H \cdot R^H \qquad (IC_L)$$

The government maximizes its expected social benefit $E\left[SB\right]$. Participation constraints (PC) enforce the non-negative profit for both types of R&D investment from the firm perspective. Incentive compatibility (IC) constraints in turn, enforce that firms weakly

prefer to adhere to the signal that best represents their patent's innovation type. They are designed so that innovation of type i is not signalled as type $-i$. This would allow firms to receive remuneration and financing destined for type $-i$ while only delivering and spending on their true type. For instance, developers of innovation type L will weakly prefer to signal type L and obtain expected sales at prices that match the patent type, than to lie and pretend to provide an innovation of type H while their cost structure aligns with type L.

Lemma 3 *In the maximization problem of the government under hidden information and incentive alignmnent, constraints PC_L and IC_H are made redundant.*

Proof for type H: From the initial model description we know that the social return of patents type H is higher than that of type L, $r^H > r^L$. From a price perspective, it is assumed that $r^H > r^L$ and it can initially be assumed that $p_H > p_L$, a higher remuneration to the type H is expected as long as social surplus is not hindered. Finally from a cost perspective, R&D is more expensive for innovation of type H than for innovation type L, though unit production cost is equal for both, $c_R^H > c_R^L > c_p$. These conditions are sufficient to deduce that the problem can be simplified.

Constraint IC_L implies constraint PC_L: If by truthfully signalling type L, the firm obtains a profit greater than the profit it would obtain when signalling type H, then PC_L is satisfied. As it is known that $p^H > p^L > c_R^L$, the right side of constraint IC_L is made non-negative, thus making constraint PC_L redundant.

Moreover, constraint IC_H is always satisfied. Since it is initially assumed that $p^H > p^L$, though nothing is determined between p^L and c_R^H the left side of the inequation will always be greater or equal than the right side. Hence, constraint IC_H is made redundant.

5.2.2 Solving incentive conflicts

Having simplified the model, the next step remains to solve it and determine what characterizes the optimum. This can hint at how information asymmetry on the type of patent affects the share of R&D costs shared as well as total profits.

Lemma 4 *Under hidden information, the contract proposed by the government to type H is distorted in order to keep incentives aligned and keep type L from misdirecting R&D investments, this results in a suboptimal solution that does not incentivize high-innovation patents.*

Proof: The simplified maximization problem can be rewritten as follows:

$$\max_{R^i,\psi^i} \quad \rho\left[\gamma(r^H - p^H)\cdot S(R^H) - \psi^H \cdot c_R^H \cdot R^H\right] + (1-\rho)\left[(r^L - p^L)\cdot S(R^L) - \psi^L \cdot c_R^L \cdot R^L\right]$$

s.t.

$$\gamma(p^H - c_p)\cdot S(R^H) - (1-\psi^H)\cdot c_R^H \cdot R^H \geq 0 \qquad (PC_H)$$

$$(p^L - c_p)\cdot S(R^L) - (1-\psi^L)\cdot c_R^L \cdot R^L \geq (p^H - c_p)\cdot S(R^L) - c_R^L \cdot R^L + \psi^H \cdot c_R^H \cdot R^H \qquad (IC_L)$$

Constraint IC_L must necessarily be binding in order to maximize the expected social surplus and extract all possible surplus while matching the allocation of cost-sharing to the type of patent. Moreover, it also implies that truthfulness is guaranteed and type L does not signal a patent type H to obtain a higher profit in the sales period. A similar reasoning is applied

to constraint PC_H which becomes binding in order to ensure participation of type H while sufficiently avoiding any incentive for type L to manifest an untruthful signal.

The goal is to discriminate the R&D support given by the government. Solving PC_H for ψ^H and using the result to solve IC_H for ψ^L provides the relations exhibited in equations (9) and (10). These two equations define ψ^i over the R&D capacity build-up and are then used to replace ψ^i in the objective function.

$$\psi^H = 1 - \frac{\gamma(p^H - c_p) \cdot S(R^H)}{c_R^H \cdot R^H} \tag{10}$$

$$\psi^L = [(p^H - c_p) \cdot S(R^L) + c_R^L \cdot R^L - \gamma \cdot (p^H - c_p) \cdot S(R^H) - (p^L - c_p) \cdot S(R^L)] \cdot \frac{1}{c_R^L \cdot R^L} \tag{11}$$

By using (10) and (11) to replace ψ^i into the objective function of the government the R&D capacities for each innovation type can be derived. These are depicted in equations (12) and (13).

$$\bar{F}({R^H}^*_{CS;HI}) = \frac{c_R^H}{\gamma[\rho \cdot (r^H - p^H) + (p^H - c_p)]} \implies {R^H}^*_{CS;HI} = F^{-1}(1 - \frac{c_R^H}{\gamma[\rho \cdot (r^H - p^H) + (p^H - c_p)]}) \tag{12}$$

$$\bar{F}({R^L}^*_{CS;HI}) = \frac{c_R^L}{r^L - p^H} \implies {R^L}^*_{CS;HI} = F^{-1}(1 - \frac{c_R^L}{r^L - p^H}) \tag{13}$$

In order for this result to be valid, the necessary condition is that $0 \leq 1 - \frac{c_R^H}{\gamma[\rho \cdot (r^H - p^H) + (p^H - c_p)]} \leq 1$ and $0 \leq \frac{c_R^L}{r^L - p^H} \leq 1$. This leaves a limited window of values for p^H as it must remain less than the difference $(r^L - c_R^L)$ for which incentives are aligned. A higher critical ratio at equilibrium implies an efficiency loss which concerns innovation type H. As a result, high-innovation R&D is hindered. Moreover, in order to maximize the social surplus while satisfying incentive constraints, the solution implies no change in the contract offered for innovation type L which in turn implies $p^L_{CS;HI} = p^L_{CS;FI} = (1 - \psi^L) \cdot (r^L - c_p) + c_p$. Solving incentives implies that the contract for type L is kept unchanged while the contract for type H is distorted. For coordination to be achieved it is necessary that the critical ratio $\frac{c_R^L}{r^L - p^H}$ equals $\frac{c_R^L}{r^L - c_p}$. This ultimately infers that $p_H = c_p$, *i.e.* prices for type H are pushed to marginal production costs.

$$\bar{F}({R^H}^*_{CS;HI}) = \frac{c_R^H}{\gamma[\rho \cdot (r^H - p^H) + (p^H - c_p]} \implies {R^H}^*_{CS;HI} = F^{-1}(1 - \frac{c_R^H}{\gamma[\rho \cdot (r^H - c_p)]}) \tag{14}$$

Comparing the result depicted in equation (14) to the benchmark in *Lemma 1* demonstrates that the capacity build-up for type H obtained through the R&D phase is smaller in the context of hidden information. The ratios of R&D cost-sharing in this setting are set in order to internalize the relations specified by (PC_L) and (IC_H). By obtaining $p^H_{CS;HI} = c_p$ as the selling price for innovation type H, equation (10) implies that $\psi^H = 1$. This means that, under hidden information, it is worthwhile for the government to completely finance R&D for innovation type H and sell the newly developed drugs at marginal production cost.

This scheme is not optimal; by dropping prices to marginal production costs, and fully financing innovative R&D, innovation type L has indeed no incentive to signal highly innovative R&D and only delivers low-end innovation. In the context of hidden information, firms of type L

benefit from an information rent due to the information asymmetry. In order to minimize this information rent the government would have to distort the offer for innovation type H. The final R&D cost-sharing ratio for type L is exhibited in equation (17). The price for innovation type L when production is pushed to marginal costs for patents type H is depicted in equation (18).

$$\psi^L = \left[(p^H - c_p) \cdot S(R^L) + c_R^L \cdot R^L - \gamma \cdot (p^H - c_p) \cdot S(R^H) - (p^L - c_p) \cdot S(R^L)\right] \cdot \frac{1}{c_R^L \cdot R^L} \tag{15}$$

$$= \left[(c_p - c_p) \cdot S(R^L) + c_R^L \cdot R^L - \gamma \cdot (c_p - c_p) \cdot S(R^H) - (p^L - c_p) \cdot S(R^L)\right] \cdot \frac{1}{c_R^L \cdot R^L} \tag{16}$$

$$= 1 - \frac{(p^L - c_p) \cdot S({R^L}^*_{CS;HI})}{c_R^L \cdot {R^L}^*_{CS;HI}} \tag{17}$$

$$p^L_{CS;HI} = c_p + \frac{(1 - \psi^L) \cdot c_R^L \cdot {R^L}^*_{CS;HI}}{S({R^L}^*_{CS;HI})} \tag{18}$$

Under a menu financing scheme and hidden information, incentives can be aligned and remain truthful, but innovation cannot be guaranteed. Firms type H, while fully funded, have no incentive to continue innovating as their surplus is normalized to zero. The optimal solution for the government implies appropriate screening and actively verifying the quality of the innovation to provide the right funding. This explains the case of India, and why the market continues to be so focused on low-end R&D. This type of R&D does not seek to develop new active molecules and prefers to increase generic production capabilities.

6 Discussion

The case study of India in this work provided in-depth information about its pharmaceutical industry. The country historically based it on the production of generics to leverage the workforce and gain a competitive production advantage in the field. Today, some of these branded generics have become large established corporations that participate in the supply of generic medicines to the global demand, making the country "the pharmacy of the world". Simultaneously, the government has led several initiatives to promote the development of new products and innovator drugs, though not real shift has been observed within the market. If innovative R&D is to be developed in India, it is of no surprise that it would be led through branded generics. This is because the country has a history of promoting the domestic industry instead of multinational companies already active in the innovative R&D pharmaceutical industry. The support received from the government is insufficient, and is translated by the product portfolios of companies that comprise an almost negligible share of innovator products. This answers the first sub-question of this research regarding the market dynamics of the country. Among the studied coordination mechanisms, it was determined that R&D cost-sharing would allow the best performance in coordinating the relationship, as the main source of price asymmetry for innovator drugs is R&D expenditures.

Regarding the choice of tools to model the government-firm relationship, as per the second sub-question, this was achieved through R&D cost-sharing. Such a mechanism showed that high- and low-innovation firms could be optimally encouraged if screening is made possible. In a context of full screening, R&D cost-sharing displayed that coordination can be achieved between a government and a branded pharmaceutical firm, be it in a setting for high- or low-innovation patents. Once the contract parameters are agreed upon, optimal production quantities are reached and the government can maximize its social surplus while guaranteeing a profit to the firm. To maintain valid results, some conditions deriving from the equilibrium are that $c_R^H \leq \frac{\gamma \cdot (p^H - c_p)}{1-\psi^H}$ for innovation type H and $c_R^L \leq \frac{p^L - c_p}{1-\psi^L}$ for type L. This infers that the mechanism coordinates if the R&D cost per unit does not surpass a certain threshold defined over the spread between the selling price and the cost of production and the share bore by the firm. As ψ^i approaches 1 the threshold tends to infinity, which indicates that the more R&D expenditures increase, the more the government will have to finance them if coordination is to be maintained. But as ψ^i approaches 1, the selling price tends to the cost of production, which is counter-productive for innovation since it cuts incentives. The contract needs to be constructed in a way that innovation is profitable. However, to maintain prices relatively low to the social surplus they bring, this occurs as the ratio of cost-sharing tends to one. In this sense, the parties involved need to negotiate acceptable profit-sharing thresholds while considering the R&D financial support coming from the government.

To discuss the model, a numerical example could consider two products with the same demand to keep the illustration simple. The parameters for high- and low-innovation drugs are depicted in table 3. Applying a centralized optimization as in section 5.1.1 would yield, as per equation(4), $F(R^H) = 0.596$ with $R^{Ho} = 31.676$ units for innovation type H and $F(R^L) = 0.500$ with $R^{Ho} = 30.000$ units for innovation type L with expected sales of 28.004 and 27.247 units respectively. For innovation type H, no coordination between the government and the firms this yields a total social surplus of 1.288.207$ for the government, but a negative profit for the

pharmaceutical firm of $-535.504,82$\$, i.e. a total surplus of $752.702,18$.

Parameter	Value	Description
D	$\mathcal{N}(30.000, 6.900^2)$	Monthly demand for cardiac medicines.
c_R^H	\$20	R&D cost per unit, type H
p^H	\$40	Selling price per unit, type H
γ	10%	Success probability for drugs type H
r^H	\$500	Marginal societal benefit, type H
c_R^L	\$5	R&D cost per unit, type L
p^L	\$10	Selling price per unit, type L
r^L	\$15	Marginal societal benefit, type L

Table 3: Parameters and descriptions relating to the numerical example

This serves as a representation of the situation in India as to why firms prefer to maintain their activities in R&D for generic production instead truthfully signal their inventions. The results for low-quality innovation when truthfully signalling the patent without any additional incentive follows the same trend, though losses do not reach the same extent. The results for this example under the R&D cost-sharing coordination contract are exhibited in Figure 8. The choice of the right cost-sharing parameter would depend on bargain capacities of the pharmaceutical firms, their

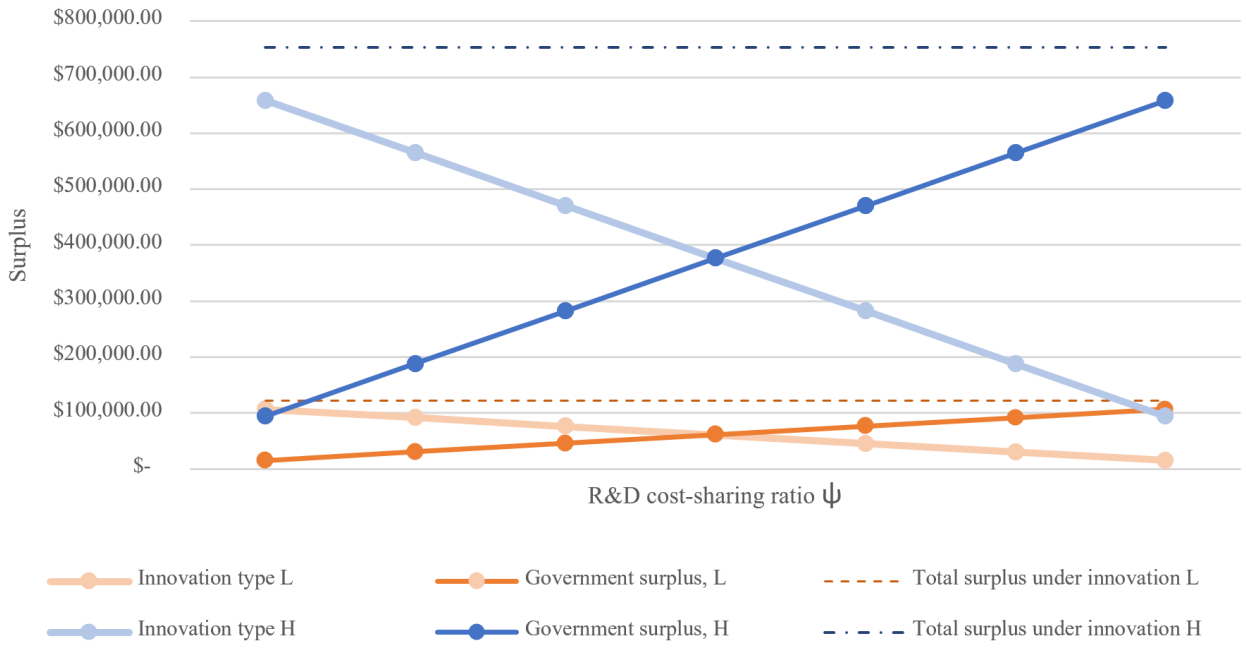


Figure 8: Example of R&D coordination through investments cost-sharing under full screening

The model showed that if full screening is made possible, the government can interact separately with firms providing high and low innovation patents. This could also serve as a way to transform the concept of compulsory licensing into a collaborative approach. Firms that would truthfully file for low-innovation patents could be rewarded by obtaining compulsory licenses of patents from firms untruthfully signalled. The concept of selling in alternate

markets introduced in the review could also be applied using this setting. The government could coordinate R&D capacity build-ups destined for different markets, populations, or patient segments.

This brings us to the topic of hidden information and the final sub-question, high-innovation R&D is not incentivized if the government does not allocate sufficient screening resources. In order to maintain objectives, the cost-sharing ratios can internalize the incentive constraints to provide the production quantities. Considering the validity conditions derived from equations (18) and (19) an example calculation of R&D capacity build-ups can be computed. Discussing this, even with a conservative probability to observe a high-innovation patent of 50%, entails that the obtained R&D capacity is optimal only for innovation type L at a value for p^H equal to the cost of production. Only at this level is the optimal capacity build-up for type L achieved without it being signalled as a high-innovation patent. Build-up of R&D capacity for type H is capped at around 24.000, implying a loss of efficiency on highly innovative R&D.

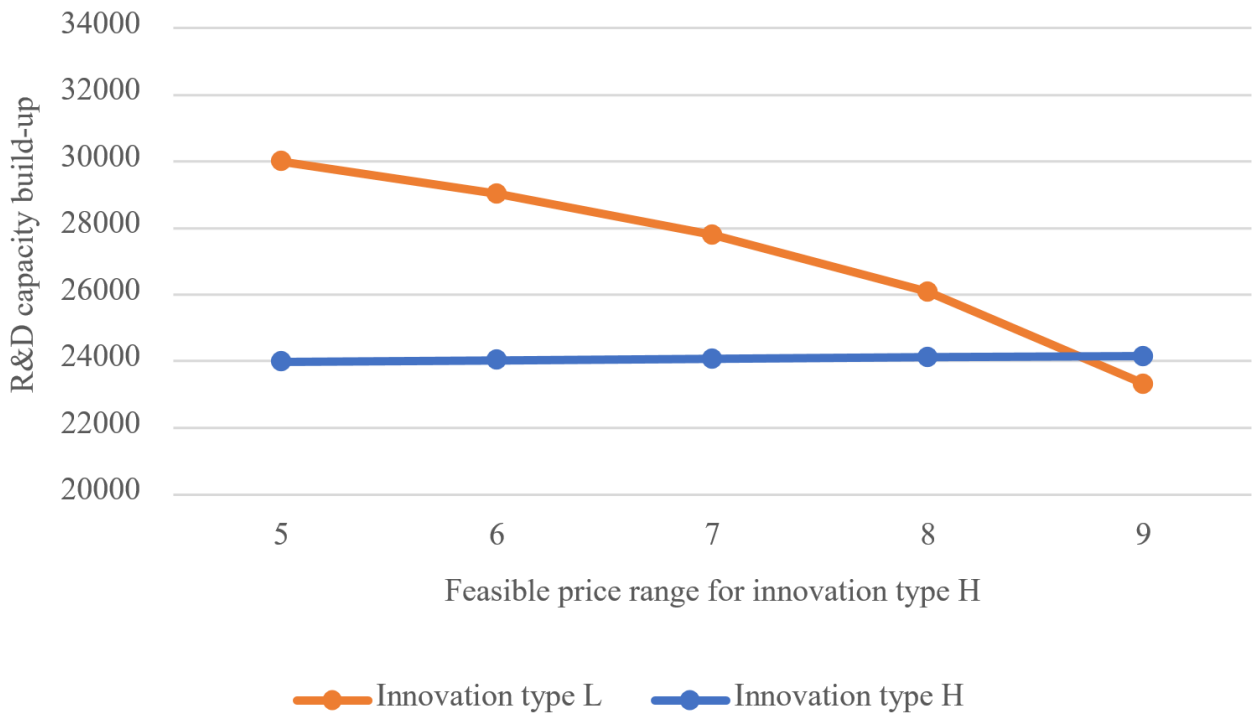


Figure 9: R&D capacity build-ups under hidden information

This aligns with the observations of the Indian pharmaceutical industry; as prices for innovative medicine increase, even when obtaining financial incentives for the government, evergreening becomes more profitable. In addition, regarding production linked incentives in India, these imply that investments could be used for generic production primarily, meaning government investments seeking to promote high-innovation R&D are misdirected. Only when type H prices are dropped at marginal costs will incentives still be controlled and optimal production quantities for type L be achieved. If innovation is to be achieved, all highly-innovative firms would need to become government-dependent and R&D expenses should be fully covered; a sub-optimal result.

7 Conclusion

7.1 Theoretical conclusions

Under the assumption that R&D expenditures are the main sources of price asymmetry regarding innovator and non-innovator drugs, the cost-sharing mechanism yields an optimal solution by distributing the load between agents. Modeling the government-firm relation via coordination contracts contributes a novel approach to the literature on public policy as typical mechanisms such as taxes and/or subsidies are not here considered. An important assumption for this was the benevolence of the government, which, as mentioned before, comes with the historical background of cooperation the Indian government has had with its domestic pharmaceutical industry. This contract ensures that the unit selling price does not surpass the marginal social benefit generated by sold drugs. To determine the right combination of price and cost-sharing parameters, a phase that considers the bargaining power of the pharmaceutical firm and the political leverage of the government could be implemented. As the cost-sharing ratio tends to one, the government must be aware of the impact on the price per unit the firm gets in order to maintain a sufficient profit that boosts innovation incentives. The contribution of this work lies as well on the analytical approach taken for stylizing a government-firm model based on empirical and historical evidence obtained in the case study.

Some critical insights were obtained when considering hidden-information. This setting was inspired by the current industry situation in India, where patents are not discriminated by the quality of their innovation and government investments aim at common facilities and incentives, *i.e.* are accessible for high- and low-level innovation products. This work's contribution demonstrated that these impersonal relations end up in the cut of high-level incentives, since firms find it more profitable to use it for the R&D of generics processes instead of new innovative processes. This research took a novel approach by combining coordination mechanisms in a setting of adverse selection to compare ensuing results. This further highlighted the importance behind screening and appropriate rewards for high-type innovation efforts. The consideration of hidden information impacts the optimal solution as cost-sharing ratios are constructed to internalize incentive alignment. This new model distorts the contract of type H by negatively affecting the price. Under this novel setting, the obtained R&D capacity build-up of type H is also hindered. Applying a cost-sharing coordination contract under hidden information resolves in sub-optimal solutions that may cut innovation incentives.

7.2 Policy-related conclusions

The present research provided a blueprint for policy-makers that aim at improving the capabilities of their country to develop high-innovation pharmaceuticals with industries typically devoted to generics production. Taking the case of India as benchmark, this research demonstrated the importance of directing a strategic mixture of resource allocation and incentive alignment, alongside proper regulation, to foster innovative R&D. However, this context does not aim at choosing one type of innovation over the other, namely innovator drugs against generics' R&D, but rather allowing both sectors to thrive. Only through proper coordination and screening can both sectors flourish. Countries with comparable pharmaceutical industries, such as Brazil or South Africa, can also make use of the findings in this research to observe the efficiency losses that are brought by improper screening, support,

and incentive alignments of firms. Many other countries also have large generic pharmaceutical industries and the sector evolves worldwide as a function of relative costs, geo-politics, and industrial-sector policy, implying the findings of this work are therefore generally applicable. India's pharmaceutical sector served as the reference setting of an industry where generic production prevails and allowed to explore and explain the intricacies of government-based coordination. The country's industry has evolved as a major force in the global pharmaceutical country. It should be expected that the next step would be leveraging the existing industry and infrastructure to reach a dual role as a generics leader and hub of innovation for cutting-edge drugs. This research exposed the challenges that exist if the country is to follow this path as it is not sufficient to allocate investments if these do not account for firms' incentives.

The research question aimed at identifying the optimal conduct through which a government can foster innovation with a generic-predominant industry. The findings in this thesis imply that in order to conduct a proper maturation of the high-quality R&D, general investments from the government that do not distinguish the type of innovation cannot guarantee incentive alignment without efficiency losses. Policy makers need to consider the historical context of the industry and current market dynamics if they are to leverage the existing infrastructure of branded generics for high-level R&D. The lack of proper screening also implies higher public spending as incentive alignment calls for full financing of high-quality R&D while pushing prices down to marginal costs. With these results, the incentives to venture in high-quality R&D drop to zero. This explains why only three branded generics, which are among the five largest generics firms in India, enter these investments out of the whole generics industry, and at an almost negligible share of 1% their product portfolio. Hence, the potential behind the investments proposed by the Indian government lack tailored incentive structures that cater the needs of innovator product development.

Developed non-innovator pharmaceutical industries, as that of India, can take a pivotal role in the future of medicines if they receive optimal targeted support, which is possible. Identifying the type of innovation requires additional spending and resources. The opportunity cost between not spending sufficient screening resources and suffering from efficiency losses under hidden information is also important to considerate. Coordinating operations with firms willing to enter high-level innovation schemes can implement contracting that optimally distributes the weight of high-level R&D expenses. Cost-sharing in the context of domestic industry promotion with transparent government forecasts enhances the relationship between government and branded generics for high-level R&D and traditional generic R&D. Through this mechanism, both types of innovation are encouraged to engage while maintaining a positive social surplus for the government and therefore, for consumers. Only with direct coordination schemes that target specific projects can genuine innovation be encouraged. The sources as to why screening is not sufficiently implemented in India suggest that laxity is in play and not enough resources are allocated as they should be. In this sense, this research also suggested that proper screening could also improve the procedure of compulsory licensing, rewarding firms that truthfully reveal their innovation quality, while applying compulsory licenses to firms that do not.

7.3 Contributions to CSR

The analysis presented in this work provides a scope to align societal considerations when determining production and pricing of pharmaceuticals. The basis of the coordination contract revolves around the consideration of the marginal societal benefit each sold drug achieves. This implies that the optimal solution is found by maximizing the social benefit obtained by the production of pharmaceuticals. The present research encourages pharmaceutical managers to reconsider CSR when determining development and production decisions instead of perceiving it as a compliance procedure. Considering CSR also highlights its potential when driving high-end R&D as optimally promoting new innovation enables new discoveries with greater societal impact. In the case of pharmaceuticals, newly developed pharmaceuticals can lead to numerous benefits since their impact encompasses healthcare savings, improved quality of life, or even synergies across sectors. Pharmaceutical firms driving high-end innovation not only contribute to an increase in revenue and product portfolio diversification. These firms contribute to social security of their nations too. Even more, by coordinating decision with governments, these firms are able to act as drivers for the affordability and availability of new treatments

7.4 Critique and outlook

This work considered the coordination between government and firm of R&D investments in generic-dominated pharmaceutical markets. The model assumed symmetry for demand information, which is applicable to the case of India due to the intense presence and knowledge firms have in the market, as well as for the history of collaboration the government has had with them. This might not be the case in other countries, where generic producers are not as predominant. Additionally, an important assumption for the feasibility of this model is that the government is able to measure *a priori* the marginal social benefit that sold drugs may have. This parameter can be estimated through existent econometric and numerical methods. However, the estimation might prove difficult if not sufficient data is available. This can be the case if, for instance, the scope and nature of the disease to treat is unprecedented, as it was the case with COVID-19.

Still concerning the marginal social benefit, coordinating R&D implies that the price of the drug will not surpass its social benefit as demonstrated in section 5.1.1. This takes on the perspective of the government and not the consumer. Section 4.1 documented the active role that the government takes on capping drug prices. Ultimately, this implicates that if to protect the consumer prices are capped to a value less than the prices estimated through coordination, then the government should reimburse the difference to the firm.

Risk-aversion is also not considered and could potentially lead to new findings. Firms might avoid venturing in high-end R&D due to the uncertainty behind developing new molecules, which would require the inclusion of risk-aversion in the analysis. Incentive misalignment is only considered on the firm's side. The model could also be developed to include corruption or incentive misalignment in the government's side. Importantly, this research mentioned further application of this model into a setting of sales through alternate markets and territories. This could include a collaboration mechanism between innovative and non-innovative firms to increase total production. Other potential research subjects could delve into the capabilities

of the government to coordinate R&D expenses in different health systems mentioned here: the Bismarck, the Beveridge, and the private model. Finally, further investigating the barriers to high-end R&D also characterizes a research on its own and could yield valuable insights on how R&D can be better coordinated.

To summarize, a government with a traditionally non-innovative pharmaceutical industry must proactively and directly engage in R&D screening to promote the development of complex high-tech products. Availability and affordability of innovator products achieved through coordination implies that financial investments are not sufficient if they address the general industry instead of targeting high-end breakthroughs. The unique capabilities of branded generics as well as their willingness to venture in high-innovation R&D can be leveraged through full information. The predominance of generic production hinders new breakthroughs if financial investments are not distinguished nor targeted. If India truly aims at encouraging innovative R&D, it must proactively screen potential projects to target funding towards high-value novel molecules while keeping branded generics available for its population.

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Note

This research contains excerpts of some of my own previously conducted work in the context of the Term Paper in the course LLSMS2035-Supply Chain Coordination and Sourcing, "Coordination contracts in the pharmaceutical industry - A review" which served as an initial sketch of the literature review for this thesis.

8 Annexes

8.1 Appendix A: List of tables and figures exhibited in this thesis

Figures and tables with their respective titles and location are presented here.

Label	Title	Section	Page
Figure 1	India's department of pharmaceuticals budget decomposition, 2022-2023	Section 4.1	Page 17
Figure 2	Key market players and figures of the Indian pharmaceutical industry	Section 4.1	Page 18
Figure 3	Decomposition of top branded generics' activities	Section 4.1	Page 19
Figure 4	Decomposition of patent filings by innovation and scrutiny	Section 4.2	Page 22
Figure 5	India's R&D-Sales ratio throughout the years.	Section 4.3	Page 23
Figure 6.a	Example prices of medicines from branded generics with high variations in prices.	Section 4.3	Page 24
Figure 6.b	Example prices of medicines from branded generics with low variations in prices.	Section 4.3	Page 24
Figure 7	Sequence of events.	Section 5	Page 26
Figure 8	Example of R&D coordination through investments cost-sharing under full screening	Section 6	Page 35
Figure 9	R&D capacity build-ups under hidden information	Section 6	Page 36
Table 1	Sales value and volume for largest segments of medicines, India, July 2020	Section 4.3	Page 24
Table 2	Summary of notations and sequence of events	Section 5	Page 26
Table 3	Parameters and descriptions relating to the numerical example	Section 6	Page 26

8.2 Appendix B: Figure 1, Indian department of pharmaceuticals budget - Python script for a Sanskey diagram

The following code snippet was created to display the diagram seen in Figure 1. Data was manually extracted and transformed to US dollars from the official budget report listed in the bibliography.

```
import plotly.graph_objects as go

labels = [
    "Total Budget, 27.54",
    "Infrastructure, 0.52",
    "Projects & Schemes, 26.45",
    "Research Institutes, 4.29",
    "Generics Stores, 0.89",
    "Pharma Industry Dev., 1.23",
    "Production linked incentives, 19.97",
    "Bulk drug parks, 15.82",
    "Medical device parks, 4.16",
    "Investment in public pharma companies, 0.47",
    "Other, 0.62",
    "Promotion, 0.02",
    "Common Facilities, 0.44",
    "Tech upgrade, 0.76"
]

source = [0, 0, 2, 2, 2, 2, 2, 2, 6, 6, 5, 5, 5]
target = [1, 2, 3, 4, 5, 6, 9, 10, 7, 8, 11, 12, 13]
value = [0.52, 26.45, 4.29, 0.89, 1.23, 19.97, 0.47,
0.62, 15.82, 4.16, 0.02, 0.44, 0.76]

node_colors = [
    'blue', 'orange', 'green', 'red', 'purple',
    'brown', 'pink', 'grey', 'yellow', 'teal', 'lightblue', 'plum', 'lightgreen']

fig = go.Figure(data=[go.Sankey(
    node=dict(
        pad=18,
        thickness=20,
        line=dict(color="black", width=0.5),
        label=labels,
        color=node_colors),
    link=dict(
        source=source,
        target=target,
        value=value)
    )])

fig.update_layout(
    font=dict(size=18, color="black"),
    height=800,
    width=1200,
    annotations=[dict(text="Source data: Ministry of Chemicals and Fertilizers, depart
                      x=-0.02, y=-0.05, xref="paper",
                      yref="paper",
                      showarrow=False),
                 dict(text="Units in millions of US dollars", x=-0.02,
```

```
                    y=-0.075,
                    xref="paper",
                    yref="paper", showarrow=False)])

fig.show(renderer="browser")
```

8.3 Proof of *lemma 1* for type L

The optimal capacities built through the R&D phase in a centralized coordination contract for types H and L are given by:

$$R_C^{H^o} = F^{-1}\left(1 - \frac{c_R^H}{\gamma \cdot (r^H - c_p)}\right); R_C^{L^o} = F^{-1}\left(1 - \frac{c_R^L}{(r^L - c_p)}\right)$$

Proof for type L: The objective function with upper-script C for "Centralized" is given by the following profit and expected profit functions:

$$\max_{R^L} \Pi_C^L = (r^L - c_p) \cdot \min\{x^L, R^L\} - c_R^L \cdot R^L$$

$$\max_{R^L} E\left[\Pi_C^L\right] = (r^L - c_p) \cdot S(R^L) - c_R^L \cdot R^L$$

The expected profit function yields the FOC exhibited here below. By isolating the R&D capacity build-up the result above mentioned can be found:

$$\frac{dE\left[\Pi_C^L\right]}{dR^L} = (r^L - c_p) \cdot (1 - F(R^L)) - c_R^L = 0$$

UNIVERSITÉ CATHOLIQUE DE LOUVAIN
Louvain School of Management

Place des Doyens, 1 bte L2.01.01, 1348 Louvain-la-Neuve
Boulevard Emile Devreux 6, 6000 Charleroi, Belgique
Chaussée de Binche 151, 7000 Mons, Belgique

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