

Peri-Urban Pharmaceutical Markets in Maharashtra, India



**Center on Democracy, Development, and the Rule of Law
Freeman Spogli Institute
Stanford University**

Advised by: Grant Miller, PhD

**Hadley Reid
Class of 2016 | Human Biology**

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Abstract

The Indian pharmaceutical market is a pharmaceutical market dominated by branded generics—higher-priced trade-marked off-patent medications. This is surprising given that India is a low-middle income country with a largely credit-constrained population. I use the case study of peri-urban Maharashtra to demonstrate that the conception of a branded generic pharmaceutical market in India is limited by its dependence on data from pharmacy transactions alone. My research shows that true generics, given as “loose medications” dispensed directly by care providers at the clinic level, play an important and under-reported role in healthcare delivery in India. I examine medication access at the informal clinic level as well as the formal pharmacy level to propose a new provider decision driven framework that includes influences at both a dispensing, primary, node and at a prescribing, secondary, node. My model accounts for both the factors driving the informal and the formal channels medication distribution in peri-urban India. This new framework offers an alternative to existing models of the pharmaceutical market make-up and has important policy implications for increasing low-income households’ access to quality medication in peri-urban India in the future.

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Chapter 1: Introduction

In healthcare markets where the patient bears the brunt of medical costs through out-of-pocket payment, one expects that, given a basic level of quality, patients will prioritize low cost care. India is a prototypical example of such a market. The majority of healthcare, about 70% in urban areas, is accessed through the private sector, and, in 2013, 86% of this care was paid for directly out of pocket.^{1,2} However, the Indian pharmaceutical market is an anomaly in that it is dominated by branded generic medications which are higher priced than typical low-cost “true” generics, off-patent medications whose price is generally kept low through competition between multiple manufacturers. My thesis aims to explore the provider-level decision-making that shapes the Indian pharmaceutical market through both informal and formal channels to yield this surprising market outcome.

Branded generics, which are medications no longer under patent, but sold under a trademarked name at a higher price than a true generic, make up between 70-80% of the pharmaceutical retail market by volume³ in India.⁴ My thesis analyzes why branded generics remain so popular in the Indian pharmaceutical market given the presence of low cost generic alternatives in a finance-constrained environment. In addition, I will examine the presence of a bifurcated market in the private healthcare sector, wherein true generic unpackaged medications

¹ International Institute for Population Sciences (IIPS) and Macro International. 2007. National Family Health Survey (NFHS-3), 2005-06, India: Key Findings. Mumbai: IIPS.

² *Out-of-pocket health expenditure (% of private expenditure on health)*. (2015). Retrieved from World Bank Development Indicators database.

³ Market share is measured in two ways: by monetary value or by volume. Unless explicitly noted otherwise, when I refer to market share I am referring to market share by volume. Value-based market share tends to skew ratios towards innovator molecules as even a small proportion of sales by volume of these medications can manifest as a large portion of value-based market share due to the price differential between these medications and both branded and true generic medications.

⁴ India pharma 2020: Propelling access and acceptance, realizing true potential. (2010). McKinsey & Company.

are still heavily utilized. The more informal methods of true generic provision have not previously been incorporated into models characterizing the factors affecting the use of formal pharmacies and pharmaceutical networks.

I take the peri-urban setting of Thane District in Maharashtra as a case study to examine the forces at work in driving the use of both branded, higher-priced, generics as well as loose generic medicines. I draw on a set of 139 qualitative interviews with households, care providers, chemists⁵, members of the pharmaceutical supply chain, and medical representatives (medreps) conducted in Thane district over a two month period during July and August of 2015. These interviews provide a detailed micro-level look at healthcare delivery and prescription practice in this area. I will use this individual-level data to inform my hypothesis as to why the formal market structure favors branded generics in India, as well as to describe an under-characterized system of generic loose medication liberally dispensed from private clinics.

I will put forth a new framework of decision making centered around two choice nodes. The first involves the decision to dispense versus prescribe medication. Dispensed medication, also known as खुले दवा *khuli dava*, or loose medication, is kept in clinic and given with nearly every medical encounter. These medications are true generics, with no rebranding. They are bulk packaged and sold at extremely low cost to providers. Providers dispense loose medications both to provide a measure of tangible value to the clinic encounter for the patient as well as as a diagnostic tool. These widely dispensed true generics are not accounted for in formal assessments of pharmaceutical market share, but do make-up a large proportion of the medication received by low-income families accessing private health care in these areas.

⁵ Chemist is the British term for pharmacist and is widely used in India. As such the word chemist in this essay will refer to a pharmacist and a chemist shop to a pharmacy.

Therefore, deciphering the underlying factors behind dispensing practice and the purpose these medications serve, is critical to understanding the care and resources patients have access to in low-income peri-urban India.

The second choice node occurs when a provider decides to prescribe from an outside source, usually a chemist. This choice node centers around the decision of what type of medication to prescribe for a given patient: innovator molecule, branded generic, or true generic. Unlike loose medications dispensed from clinic, prescribed medication is part of the formal pharmaceutical market dominated by branded generics. There are existing models in the literature which can be applied to predict why the formal pharmaceutical market in India is characterized by a disproportionate share of branded generic medications. I explore two models of the emergence of branded generic markets. Neither model has previously been widely applied to a developing country context, I therefore update them to apply to the peri-urban Indian setting. I evaluate Danzon and Furukawa's model of brand as a proxy for quality to predict branded generic market share by in less regulated markets.⁶ I find that this model only partially explains prescription outcomes in peri-urban Maharashtra. However, I will assert that the model of brand as a proxy for quality interacts synergistically with theories of the role of medical representatives and pharmaceutical marketing, which I find to be more predictive of the branded generic market outcome in these areas. The medical representative is a crucial player in shaping the Indian pharmaceutical market. However, medical marketing has more often been studied in developed countries and its role has been under-documented in low income settings. I will explore the

⁶ Patricia, Danzon. M., & Michael, Furukawa. F. (2011, March). *Cross-national evidence on generic pharmaceuticals-pharmacy vs. physician-driven markets*. Retrieved from National Bureau of Economic Research database. (Accession No. 17226)

importance of the medrep in peri-urban India, as this influence is of increasing importance for cost containment of medical expenses in these areas.

I will begin with a background on medical practice in India including a description of provider training and the current legal landscape for healthcare in India. I will describe the methodology of the qualitative research that informs this thesis, as well as the limitations of such methods. I will then go into more depth on the existing predictive frameworks of prescription practice and pharmaceutical market outcomes before proposing my own provider decision-based model. I will validate my model through my findings on both the informal loose medication market and formal branded generic dominated medication market in peri-urban Maharashtra. Finally, I will conclude with the potential policy applications of my proposed model of a provider decision driven pharmaceutical market in these areas.

Chapter 2: Background

2.1 Medical Coverage and Types of Practitioners

In 2013 about 60% of all healthcare in India was paid for out of pocket.⁷ If this figure is limited to expenditure on private healthcare, this number shoots up even higher to 89% of private healthcare spending coming from out of pocket.⁸ Even among other low and lower-middle income countries in this region this is a high percentage of care being paid for directly by patients (Fig 1). Across India various publicly subsidized healthcare schemes exist. In Maharashtra the Rajiv Gandhi Jeevandayee Arogya Yojana program provides health insurance coverage for a set list of medical procedures performed in public hospitals for Below Poverty Line (BPL) yellow ration cardholders as well as Above Poverty Line (APL) orange ration card holders. The scheme offers up to \$2200 (₹146,564) in coverage to families earning less than \$1476 (₹98,390) per year.⁹ However, the most recent data, which date from the 2014 National Sample Survey (NSS), indicate that in urban areas of the state 85% of outpatient and 80% of inpatient hospital care is accessed through private sector facilities.¹⁰ In rural areas the numbers are comparable with 80% of outpatient care and 80.8% of inpatient care accessed through private facilities. Trends identified in the NSS are consistent with the care-seeking patterns we observed during the summer of 2015 in our field research in Thane District, a peri-urban area of

⁷ *Health expenditure ratios, all countries, selected years, estimates by country*. (2014). Retrieved from Global Health Observatory data repository database.

⁸ World Bank Development Indicators database. (2015).

⁹ Pradhan, R. (2012, December 22). Rajiv Gandhi Jeevandayee Arogya Yojana: what you need to know. *MoneyLife*, Insurance. Retrieved from <http://www.moneylife.in/article/rajiv-gandhi-jeevandayee-arogyayojana-what-you-need-to-know/30348.html>

¹⁰ Government of India Ministry of Statistics and Programme Implementation. (2016, April). *Health in India NSS 7th round (January-June 2014)* (Report No. 574) (S. Mallick, Ed.). New Delhi: National Sample Survey Office.

Maharashtra state. The scope of this thesis is therefore primarily limited to private practitioners who provide the majority of care in these areas, and in turn have the largest influence on the medication provision and the pharmaceutical market there.¹¹

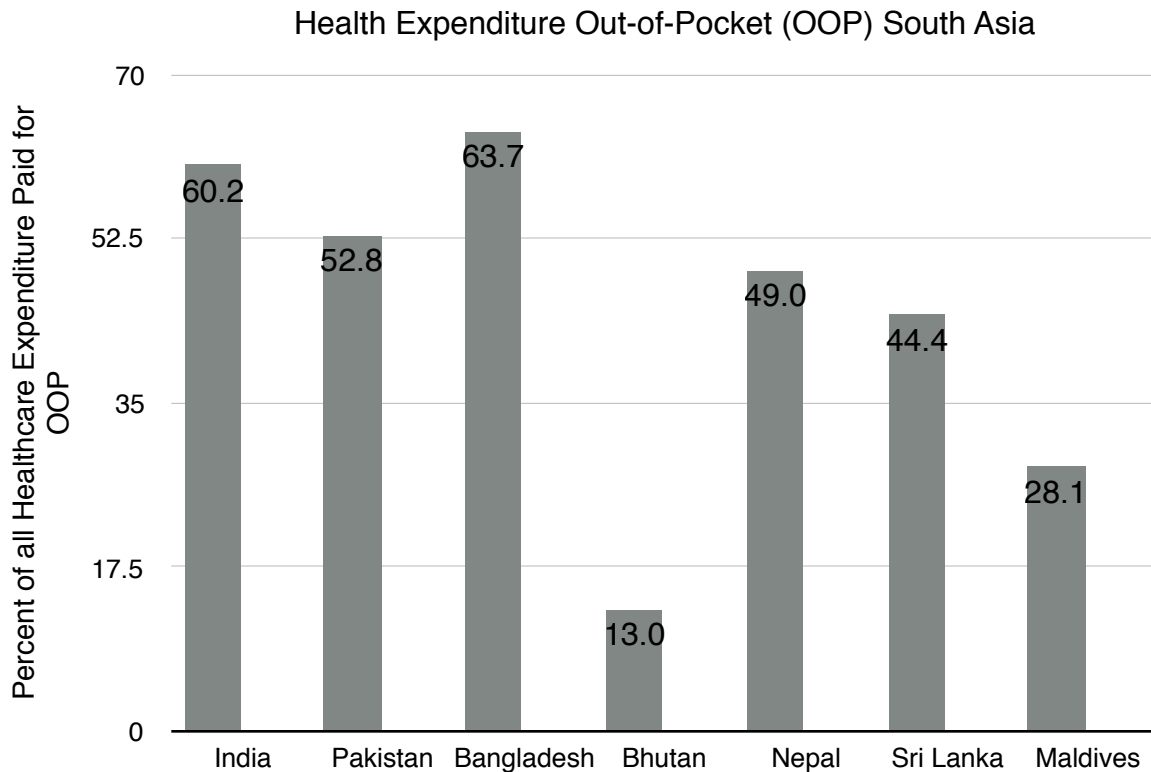


Figure 1: Out-of-pocket spending on health in the South Asian subcontinent in 2009. Data courtesy of the WHO World Health Statistics 2012.¹²

The high percentage of out-of-pocket payment and utilization of private sector care in Maharashtra, and India in general, make it an interesting place to study decisions affecting the make-up of the pharmaceutical market. Many households in Maharashtra face serious credit

¹¹ Public sector providers are also unique in that many of the medications provided through public sector care are bulk purchased by the government and provided by chemists incorporated into government facilities.

¹² World Health Organization Global Health Observatory. (2012). *World health statistics 2012: Part III global health indicators*.

constraints. In 2009-2010 the 29.5% of rural Maharashtrians lived below the poverty line¹³, while 18.3% of urban populations in the state lived below it.^{14,15} Income is distributed heterogeneously in the state. Booming urban centers such as Mumbai and Pune make up a lion's share of the state domestic product (SDP) at 21.5% and 11.1% of the SDP respectively.¹⁶ Thus, while Maharashtra is overall a relatively wealthy state, this wealth tends to be concentrated in urban centers and average income falls as one moves into peri-urban and rural areas. Healthcare spending in Maharashtra's Thane District, where our research team was based, is also credit-constrained. Only 15.7% of households there had any "usual member" covered by either a health scheme or health insurance, and on average 6.6% of monthly per capita consumption expenditure in Maharashtrian households goes to out of pocket (OOP) expenditures on health.^{17,18,19}

Households in Maharashtra clearly prioritize health spending, and the majority of this spending comes directly out of earnings and loans versus through insurance coverage.

There are a variety of types and qualifications of provider that are accessed in the private sector in India.²⁰ MBBS providers are trained in allopathic (western) medicine and are certified

¹³ The Suresh Tendulkar Committee defined the poverty line as living with 1.25 U.S. purchasing power parity dollars per day when the report was conducted.

¹⁴ Shah, M. (2013, August 5). Understanding the poverty line. *The Hindu*, Opinion. Retrieved from <http://www.thehindu.com/opinion/lead/understanding-the-poverty-line/article4989045.ece>

¹⁵ Government of India Planning Commission. (2014, June). *Report of the expert group to review the methodology for measurement of poverty*.

¹⁶ Jayachandran, U. (2014). *United Nations Development Programme: Maharashtra human development report 2012: towards inclusive development*. New Delhi, India: SAGE Publications India Pvt Ltd.

¹⁷ Government of India Ministry of Health and Family Welfare. (2016). *District fact sheet Thane Maharashtra*. Mumbai, India: International Institute for Population Sciences.

¹⁸ The all-country average is 5.7% of monthly per capita expenditure going towards OOP healthcare spending.

¹⁹ Mohanty, S. K., Chauhan, R. K., Mazumdar, S., & Srivastava, A. (2014). Out-of-pocket expenditure on health care among elderly and non-elderly households in India. *Social Indicators Research*, 115(3), 1137-1157.

²⁰ Provider degrees and training vary in the public sector as well. There are certain positions reserved for specialists of alternative medical practice in public hospitals. In practice, providers with degrees in alternative medicine may take on positions in western medicine to fill vacancies in public hospitals, however this practice is not legally condoned.

to practice as generalists after four and a half years of schooling and a year-long internship. Ayurvedic, Yoga and Naturopathy, Unani, Siddha, and Homeopathic (AYUSH) providers are trained in their particular field of alternative medicine. Five and a half year degree programs exist for each type of traditional medicine, however the Bachelor of Ayurvedic Medicine and Surgery (B.A.M.S.), Bachelor of Unani Medicine and Surgery (B.U.M.S.), and Bachelor of Homeopathic Medicine and Surgery (B.H.M.S.) are the by far most popular (Fig. 2).²¹ There were 737,000 legally registered²² AYUSH practitioners in India in 2015, of which Ayurvedic practitioners alone made up over 50%. Maharashtra is one of the states with the highest number of registered AYUSH practitioners.

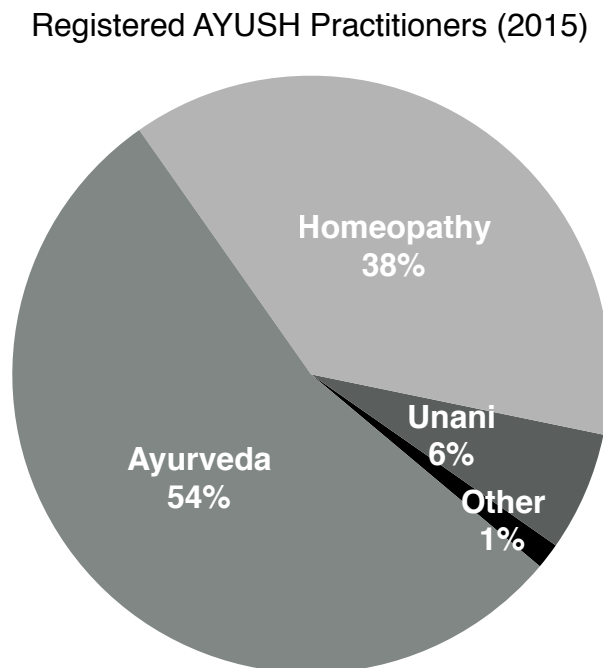


Figure 2: Registered AYUSH practitioners across India in 2015.

²¹ 7.37 lakh practitioners, 3600 hospitals for alternative medicine in India. (2015, April 28). *dnaindia*, Health. Retrieved from <http://www.dnaindia.com/health/report-737-lakh-practitioners-3600-hospitals-for-alternative-medicine-in-india-2081461>

²² As with any weakly regulated country this number far under-estimates the true number of these providers actually practicing in the country.

The Ayurvedic, Unani, and Homeopathic curriculum for each respective bachelor of medicine and surgery focuses mainly on the tenants of the medical specialty. Anatomy, physiology, minor surgery, and basic diagnostic analysis are also part of the curriculum of these degrees, although each subject is taught through the lens of the respective discipline of traditional medicine.^{23,24} The demand for strictly traditional medical care is low in India. In 2014 the National Sample Survey found that allopathic care was preferred in 90% of cases by both rural and urban populations.²⁵ There is also a well-documented shortage of allopathically trained medical professionals in India. In 2012 there was about one physician, either general practitioner or specialist, per 1430 people.²⁶ While this scarcity is more pronounced in rural areas, low-income urban areas also suffer from a dearth of western-trained medical personnel.

These factors and a weak regulatory system have combined to encourage the allopathic practice by Ayurvedic, Unani, and Homeopathic practitioners. While technically illegal in Maharashtra until recently this practice has been tacitly condoned for many years, in part due to a weak and understaffed regulatory body in the state. The curriculum for Ayurvedic, Unani, and Homeopathic training contains a one year long internship as part of the five and a half year degree of which six months is usually spent at an allopathic hospital. While the trainee is not allowed to practice allopathy during this time, the experience certainly serves as exposure to the

²³ Ayurveda syllabus/curriculum. (n.d.). Retrieved 2016, from Central Council of Indian Medicine website: <http://www.ccimindia.org/ayurveda-syllabus.php>

²⁴ Unani syllabus/curriculum. (n.d.). Retrieved 2016, from Central Council of Indian Medicine website: <http://www.ccimindia.org/unani-syllabus.php>

²⁵ Singh, M. (2015, July 8). 90% of Indians prefer allopathy over AYUSH. *The Times of India*, India. Retrieved from <http://timesofindia.indiatimes.com/india/90-of-Indians-prefer-allopathy-over-AYUSH/articleshow/47981441.cms>

²⁶ *Physicians (per 1,000 people)*. (2015). Retrieved from World Bank Development Indicators database.

western medical system and was often cited by practitioners in our area of study as one of the reasons they felt comfortable practicing allopathy under their AYUSH degree.

It is important to distinguish B.A.M.S., B.U.M.S. and B.H.M.S. degreed providers from truly informal providers or “quacks.” These are providers with no true formal training, or with fraudulent or unrecognized degrees such as those in Electrohomeopathy or the outdated title of Registered Medical Practitioner (RMP). Truly informal providers still practice in India, often taking advantage of a the lack of appropriate registered medical providers as well as gaps in law enforcement. However, in urban areas where there tend to be more licensed providers, both of traditional medicine who practice allopathy and of allopathically trained MBBS doctors, informal providers play less of a role than in rural settings. Throughout this thesis I will refer to private general practitioners in our area of study. This term then denotes any MBBS doctors, any AYUSH certified providers who practice allopathy, as well as the small number of true “quacks in our area of study.

2.2 Legislation and Regulation

A basic understanding of the legal framework for medical practice in Maharashtra is necessary to put allopathic practice by traditionally trained providers into context. In 2015, when we conducted our research, Ayurvedic and Unani practitioners were legally allowed to practice allopathy in Maharashtra. Unani and Ayurvedic practitioners had been tacitly allowed to practice allopathy under two notifications in 1992 and 1999 by the Maharashtra State Legislature.²⁷

²⁷ Tembhekar, C. (2014, February 27). Bill amended to let Ayurveda, unani doctors practise allopathy. *Times of India*. Retrieved from <http://timesofindia.indiatimes.com/city/mumbai/Bill-amended-to-let-ayurveda-unani-doctors-practise-allopathy/articleshow/31072628.cms>

However, it was not until 2014 when the Maharashtra Act No. XXVIII formally amended the Maharashtra Medical Practitioners Act of 1961 that Ayurvedic and Unani practitioners were formally given “the privilege to practice the modern scientific medicine known as allopathic medicine to the extent of the training they received in that system.”²⁸ Registered Unani and Ayurvedic practitioners do not have to participate in any continuing learning courses to prescribe allopathic medications and perform minor surgeries. Homeopathic providers, however, are only allowed to prescribe allopathic medicine after completing a one yearlong pharmacology bridge course. This course was established in 2014 by an amendment to the Maharashtra Medical Council Act of 1965 and the Maharashtra Homeopathic Practitioners’ Act.^{29,30}

The pharmacology course itself continues to face challenges as, as recently as September 2015, reputable medical colleges have refused to offer the course. Furthermore, enrollment in the course is limited to Homeopaths with at least ten years of experience, thereby preventing newer graduates from legally practicing allopathy. The first iteration of the yearlong course launched in November 2015 at selected medical colleges.³¹ Thus, at the time of our research, Unani and Ayurvedic practitioners were legally allowed to prescribe allopathic medicine. Meanwhile Homeopaths had the opportunity to become certified to practice allopathy through a yearlong

²⁸ Maharashtra Medical Practitioners (Amendment) Act, 2014 (Mah. Act XXVIII of 2014) English translation. Retrieved from <http://bombayhighcourt.nic.in/libweb/acts/Stateact/2014acts/2014.28.PDF>

²⁹ Gwalani, P. (2014, June 15). Upset IMA to move against state. *The Times of India*. Retrieved from <http://timesofindia.indiatimes.com/city/nagpur/Upset-IMA-to-move-court-against-state/articleshow/36592289.ms>

³⁰ The Maharashtra Homeopathic Practitioners’ and the Maharashtra Medical Council (Amendment) Act, 2014 (Mah. Act No. XIX of 2014). English Translation. Retrieved from <http://bombayhighcourt.nic.in/libweb/acts/Stateact/2014acts2014.19.PDF>

³¹ Gwalani, P. (2015, September). GR holds hope for pharmacology course for homeopaths.”*The Times of India*. Retrieved from <http://timesofindia.indiatimes.com/city/nagpur/GR-holds-hope-for-pharmacology-course-for-homeopaths/articleshow/48992336.cms>

pharmacology course, but the delay in implementation meant that no homeopathic practitioners could have technically taken the course and thereby legally practice allopathy as of July of 2015.

Medications in India fall into one of several schedules as defined by the Drugs and Cosmetics Rules of 1945.³² Scheduled medications are not dispensed over the counter (OTC), and, depending on the schedule, may have additional regulatory guidelines on their sale or storage. Schedule H, H1, and X are the most commonly encountered schedules of medication. Schedule H medications can only be sold with the valid prescription of a registered medical provider. Schedule H1 medications are slightly more restricted. They can only be sold upon a valid prescription, and the retailer must keep a record of their sale for possible inspection. Currently Schedule H1 includes newer tuberculosis medications as well as third and fourth generation cephalosporins and other antibiotics. Schedule H1 is a newer schedule of medications which was implemented in early 2014 due to the failure of Schedule H classifications to prevent rampant OTC dispensing. Finally Schedule X medications include narcotics and require prescription in duplicate as well as meticulous record keeping on the part of the chemist. Confusion remains among chemists as to whether prescriptions for medications, especially Schedule H1 medications, from Ayurvedic, Homeopathic, and Unani trained providers should be accepted as valid.³³

Providers in our area of study commonly kept medications in clinic which they dispensed with consultation. This practice is legal under the Drugs and Cosmetics Act of 1940. The act only stipulates that in order to keep medications in clinic providers must maintain a register of

³² Hazra, A. (2014). Schedule H1: hope or hype? *Indian Journal of Pharmacology*, 46(4), 361-362.

³³ Schrivastav, S. (2014, February 28). 46 drugs under strict prescription norm. *The Times of India*. Retrieved from <http://timesofindia.indiatimes.com/city/nagpur/46-drugs-under-strict-prescription-norm/articleshow/31123649.cms>

purchase for schedule H medications, and medications must be properly stored. Guidelines laid out by the Medical Council of India (MCI) indicate that doctors cannot separately charge patients for medications, but they can stock medicines as “per requirement of patients.”³⁴ Thus, doctors are not allowed to keep bulk supplies of medications, especially those of higher antibiotics and other schedule drugs, which have more stringent storage requirements. Food and Drugs Administration (FDA) inspections by a severely understaffed³⁵ inspection force supposedly enforce these vague guidelines. Chemist trade boards have periodically pushed for the banning of provider dispensed medications. However the FDA has so far rejected these proposals from these bodies.³⁶

Chemist shops have their own restrictions and regulations. Since the 1948 Pharmacy Act, only a registered, degreed chemist can legally dispense medicine based on prescriptions. This regulation, however, was poorly enforced for upwards of five decades. In 2013 it was estimated that of the 50,000-70,000 chemist shops that operate within Maharashtra, only about 50% of them were consistently staffed by a registered chemist.³⁷ However, from 2011-2014 the Maharashtra FDA moved to more strongly enforce this regulation. Over 3,000 chemists were closed in Maharashtra in 2013 alone for not having a trained pharmacist present at the business.³⁸

³⁴ Andhale, S. (2014, August 6). FDA cracks down on docs hoarding medicines. *dnaIndia*. Retrieved from <http://www.dnaindia.com/mumbai/report-fda-cracks-down-on-docs-hoarding-medicines-2008330>

³⁵ Maharashtra has 120 FDA inspectors for an estimated 300,000 doctors.

³⁶ Pal, S. (2013, June 27). Medicines at doctor’s clinic may cost you a lot less. *dnaIndia*. Retrieved from <http://www.dnaindia.com/mumbai/report-medicines-at-doctor-s-clinic-may-cost-you-a-lot-less-1853729>

³⁷ Porecha, M. (2013, January 30). Maharashtra pharmacy council suspends 80 chemists for malpractice. *dnaIndia*. Retrieved from <http://www.dnaindia.com/mumbai/report-maharashtra-pharmacy-council-suspends-80-chemists-for-malpractice-1794039>

³⁸ Saraswat, S. (2013, October 16). Maharashtra chemists oppose drug panel’s decision, surrender licenses. *IndiaToday*. Retrieved from <http://indiatoday.intoday.in/story/maharashtra-chemists-oppose-fda-full-time-pharmacist-medicine-bill/1/316475.html>

Chemist shops mainly stock and providers mainly prescribe branded generics. These are generic medications; the molecule being produced is no longer protected by a product patent, whether because the patent has expired or because of the weak patent regulation in India prior to 2005. Companies will trademark these generic products and sell them under a brand name. Thus, these trade-marked medications are known as branded generics. Branded generics are not an India-unique phenomenon. In fact, the use and prescription of branded generics in developing countries is quite widespread.³⁹ However, the Indian pharmaceutical market is unique in that branded generics make up between 70-80% of pharmaceutical retail, a market share larger than almost any other country in the world.⁴⁰ This is especially notable due to the aforementioned financial constraints faced by low-income Indian consumers. Branded generics utilize the same marketing and aggressive market share accumulation strategies of innovator medications. In turn, they are higher priced than true generics in order to recoup marketing costs, but are less expensive than most innovator molecule counterparts.

The pharmaceutical marketing industry has also recently seen an increase in regulation in India. Beginning on January 1st 2015, the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) was implemented nationwide as a self-enforced industry code of conduct. The UCPMP clarifies the tolerance for gift giving and incentives from the pharmaceutical industry, stating, “no gifts, pecuniary advantages, or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharma company, or any of its agents

³⁹ Kaplan WA, Wirtz VJ, Stephens P (2013) The Market Dynamics of Generic Medicines in the Private Sector of 19 Low and Middle Income Countries between 2001 and 2011: A Descriptive Time Series Analysis. PLoS ONE 8(9): e74399. doi: 10.1371/journal.pone.0074399
Kaplan et al find Argentina with a slightly higher market share around 82% of the pharmaceutical market by volume.

⁴⁰ McKinsey & Company (2010)

including retailers, distributors or wholesalers.”⁴¹ It also states that providers must incur any costs of attending conferences or other promotional/educational events excepting physician travel to domestic conferences, which pharmaceutical companies may reimburse. Six months after implementation, the Indian government has announced that it plans to update the code to be mandatory for pharmaceutical companies after it “found it very difficult to enforce [...] a voluntary code.”⁴² The text of the mandatory code is yet to be formally announced.

⁴¹ Mukherjee, R. (2014, December 23). From Jan 1, pharma cos can no longer gift freebies to doctors. *The Times of India*, Business. Retrieved from <http://timesofindia.indiatimes.com/business/india-business/From-Jan-1-pharma-cos-can-no-longer-gift-freebies-to-doctors/articleshow/45610957.cms>

⁴² Jacob, S. (2015, September 29). Govt plans mandatory marketing code for pharmaceutical firms. *Live Mint*, Industry. Retrieved from <http://www.livemint.com/Industry/LUwGqs605S4bQkfbRglVTI/Govt-plans-mandatory-marketing-code-for-pharmaceutical-firms.html>

Chapter 3: Materials and Methods

Our research team—three Stanford undergraduate students, one Stanford medical student, four researchers from the Delhi-based Institute of Socio-Economic Research on Development and Democracy (ISERDD), and two translators—worked in peri-urban Mumbai for seven weeks conducting semi-structured qualitative interviews from July-August 2015. Our interviews focused on the pharmaceutical supply chain and prescription practice in peri-urban settings. This work built off of previous findings from the Stanford India Health Policy Initiative (SIHPI) as well as research questions proposed by a roundtable of Indian stakeholders and policy-makers conducted in January of 2015. Funding for this research was generously provided by the Policy Implementation Lab of the Freeman Spogli Institute at Stanford University.

3.1 Identifying Research Sites and Interviewees

Data was collected primarily from two towns, Bhiwandi and Ulhasnagar. Both are located in Thane district, about 20 miles north of Mumbai. Additional interviews were also conducted in two neighboring towns, Dombivli and Kalyan, as well as in Mumbai proper. Bhiwandi and Ulhasnagar were chosen as the primary research sites due to their peri-urban and low-income status, and the wide variety of providers and stakeholders involved in the healthcare system in these areas. Although urban areas of India have been shown to have greater access to healthcare facilities and resources, research has shown that both urban slums and peri-urban fringe areas may have worse health outcomes than rural areas due to unsanitary living conditions and poor access to public facilities.⁴³ The peri-urban nature of Ulhasnagar and Bhiwandi was therefore of

⁴³ Dilip, T. R., & Duggal, R. (2004). Unmet need for public health-care services in Mumbai, India. *Asia-Pacific Population Journal*, 19(2), 27-40.

interest as an understudied and underserved area with the potential for gains in health infrastructure and outcomes.⁴⁴



Figure 3: Map of areas of study.⁴⁵

⁴⁴ Peri-urban areas are transition zones between urban centers and rural areas that are characterized by lower population densities and levels of industrialization. While choices for privately provided care may not be as varied in peri-urban settings as in true urban areas, there is still a fair amount of choice of private provider in these areas. Previous studies have shown that even in truly rural areas, if formal qualifications and training of the provider are disregarded, households have access to about six providers across the public and private sector. In more densely populated peri-urban areas this number is even higher. However, as is the case in both true rural and urban settings across India, private providers in peri-urban settings are not necessarily trained in western medicine and practice with a varying degree of formal training and skill.

Das, J., Holla, A., Kremer, M., & Muralidharan, K. (2011, February). *Mapping medical providers in rural India: Four key trends*. New Delhi: Centre for Policy Research.

⁴⁵ Courtesy of LEA International Ltd. Transport Plan for MMR and Resource Generation Plan under Mumbai Transformation

Ulhasnagar and Bhiwandi were also selected as places where the research team had previously established contacts and local knowledge of the community. As the nature of our research was both time intensive and required honesty on the part of our interviewees, this local knowledge of the community was integral to our ability to gain trust and access to players in the healthcare system. These connections were, for the most part, established through one of the ISERDD team member's previous doctoral research in the area.

Ulhasnagar is divided into five areas, each known by number.⁴⁶ We focused on Ulhasnagar one, three and five. One and three had similar demographics including large populations living in bastis. Bastis (also spelled bustee or busti) are loosely defined as shantytowns.⁴⁷ In Ulhasnagar and Bhiwandi the basti areas were composed of low-lying one to two-story buildings generally composed of one to three rooms for a family. Clinics and chemists were also located within bastis or on the main roads directly outside the bastis. Ulhasnagar 5 was a more rural area of the town with a predominantly migrant population focused on jean manufacturing. The population of Ulhasnagar was primarily Hindu (82%)⁴⁸.

Bhiwandi, on the other hand, had a significant Muslim population (56%)⁴⁹, which allowed for access to Unani practitioners. As Unani medicine, a traditional form of Persian-Arabic medicine, originated in Muslim culture, Unani practitioners are, in the vast majority, Muslim themselves and treat Muslim patients. Our research sites in Bhiwandi included both

⁴⁶ This numbering system dates from Ulhasnagar's historical role as a site of military barracks during World War II. The numbering of the barracks, 1-5, is replicated in the present day neighborhood divisions of Ulhasnagar into 1-5.

⁴⁷ Spear, T. P. (2016). India. In *Encyclopaedia Britannica*. Retrieved April 18, 2016, from <http://www.britannica.com/place/India/Demographic-trends#ref972207>

⁴⁸ Census Organization of India. (2012). Ulhasnagar city census 2011 data. Retrieved from Census 2011 database.

⁴⁹ Census Organization of India. (2012). Bhiwandi city census 2011 data. Retrieved from Census 2011 database.

settlements⁵⁰ and bastis. The main industry of employment in Bhiwandi centers around power-loom weaving. Workers at the power looms earn on average 9,000 rupee (\$134.80) a month for 12-16 hour workdays.⁵¹

Within our two main field sites we followed a chain-referral sampling methodology. While this methodology has some limitations it is recommended for identifying “difficult to reach [...] populations,” such as the small-scale providers, chemists, and supply chain workers who were the primary focus of our interviews.⁵² We began by interviewing a random sample of households in each field site. We then identified and interviewed every provider mentioned in a household interview, with special emphasis on those mentioned multiple times.⁵³ This allowed us to differentiate between providers simply practicing nearby and those who were important, influential, and highly utilized providers in the community. Following interviews with these providers we spoke with additional nearby providers until we had met our pre-established quota for the area (see Table 1). Chemist interviewees were identified by their proximity to and interaction with providers and households. Stockists, distributors, wholesalers, and manufacturers were identified through interviews with chemists and practitioners and then interviewed.

Medical representatives (medreps) were identified at chemists and providers’ offices and interviewed. We also sought out medreps at known locations of medreps congregation. A

⁵⁰ While similar to bastis in terms of available services settlements tended to be set slightly further apart from the city, whereas bastis were located directly off of main thoroughfares.

⁵¹ Shaikh, Z. (2015, March 26). It has power looms, it powers the e-commerce boom, yet Bhiwandi remains a backwater. *The Indian Express*, Mumbai. Retrieved from <http://indianexpress.com/article/cities/mumbai/it-has-power-loom-it-powers-the-e-commerce-boom-yet-bhiwandi-remains-a-backwater/>

⁵² Atkinson, R., & Flint, J. (2001). Accessing hidden and hard-to-reach populations: Snowball research strategies. *Social Research Update*, (33).

⁵³ Occasionally, a provider would prove to be impossible to locate either due to confusion over name or clinic location.

previously established connection allowed us multiple interviews as well as opportunities to shadow medreps and senior marketing staff of a large multi-national pharmaceutical company.

Location	Households	Providers	Chemists	Supply Chain	Medreps
Ulhasnager	16	16	7	6	1
Bhiwandi	13	16	7	8	4
Other	4	11	2	7	9*

Table 1: Interviews conducted by actor and location. Supply chain category includes manufacturers, stockists, wholesalers, and distributors.

3.2 Qualitative Methods

We conducted semi-structured interviews ranging from 20-90 minutes in length using pre-created discussion guides for each type of interviewee: household, provider, chemist/stockist, and medical representative (see Appendix II). Interviews were conducted in Hindi, Marathi, or English depending on the preference of the interviewee. All ISERDD researchers were fluent in or native speakers of Hindi as was one Stanford researcher. Non-Hindi speakers used translators for interviews conducted in Hindi. Translators were also used for interviews conducted in Marathi. Interview teams generally consisted of one Stanford researcher, one ISERDD researcher and one translator. Observations of interview sites, including storage facilities, size, and cleanliness were recorded for each interview. Whenever possible multiple researchers took notes during each interview for crosschecking and quality assurance.

The research group debriefed every evening after fieldwork to share the main points of their interviews. Team meetings allowed for debate and eventual consensus on interviewee

statements when discrepancies were found in researcher notes. This time was also used to refine the discussion guides based on the new raw data. The data gathering process was both iterative and inductive.⁵⁴ Themes identified in interviews were incorporated into the discussion guides in order to test for reality and consistency in subsequent interviews and data collection. Meeting notes were electronically recorded daily to monitor progress and preserve original data.

Field notes and written interview transcripts were also typed daily in a collaborative editing platform, and reviewed by the researchers who were also present at each interview. Provider, chemist, and household interviews were coded into broad categories while in the field. Agreement was sought on coding and the themes that emerged from the data. The ongoing coding process allowed for pattern visualization as well as identification of gaps in our interview data. We used these gaps to recognize and re-interview players for missing information.

Further analysis for the research I present in this paper involved more fine coding of provider, household and chemist interviews. Medrep interviews were coded for themes related to marketing, relationship building, and market changes. Supply chain player interviews were used to evaluate statements of other players about supply chain practices. When logical, interview data was quantified to yield background demographic statistics as well as descriptive statistics of provider, chemist, and medrep practices.

3.3 Limitations

Our research was limited in that it was dependent on the willingness of different players in the healthcare system to speak with our team. This meant that our data suffer from a certain

⁵⁴ Kotwani, A., Wattal, C., Katewa, S., Joshi, P. C., & Holloway, K. (2010). Factors influencing primary care physicians to prescribe antibiotics in Delhi India. *Family Practice*, 27(6), 684-690.

amount of selection bias. For instance, the household members we were able to access in our interviews were generally women and older members of the household, as the men and other breadwinners tended to be at work during the times we conducted our fieldwork. This had an influence on the types of illness narratives and care-seeking experiences that were reported. However, as women tend to have greater responsibility for health, especially children's health, in the household this was not viewed as a serious disadvantage to the data collection.

There are unknowable and unobservable differences between the providers we were able to access and those that were either un-locatable, unavailable to interview or who declined to speak with our research team. While we were clear that our research was solely academic in nature, there was apprehension among both interviewees and those individuals who declined to be interviewed because of legal repercussions to some questions. This almost certainly led to underreporting of certain practices or denial of practices that do in fact occur. For example, by law chemists in Maharashtra are not allowed to give scheduled medications over the counter. However, other research has found that this is a common practice.⁵⁵ In our sample, chemists mainly denied over-the-counter dispensing of scheduled medications. There have been more stringent regulations put into place since previous accounts of this practice were recorded in the literature. Thus, our finding could indicate an effective crackdown on this practice by the Maharashtra government. However, chemists could also be underreporting a known illegal activity. The sensitive nature of our interviews and the type of data we were collecting meant that this type of underreporting is a consistent limitation to our data across our interviews with different players in the pharmaceutical networks of these areas.

⁵⁵ Kamat, V. R., & Nichter, M. (1998). Pharmacies, self-medication and pharmaceutical marketing in Bombay, India. *Social Science & Medicine*, 47(6), 779-794.

While these limitations to our methodology exist, the level of detail and nuance that we were able to collect through qualitative interviewing was an important advantage that validated the use of this methodology. I am still able to draw reasonable qualified conclusions from the data, and it provides an important base of knowledge on peri-urban medical practice in India that was nonexistent in the literature prior to this data collection.

Chapter 4: Existing Frameworks for Determining Medication Decisions

There currently exist several models designed to explain how prescription practice, is determined in different pharmaceutical markets. While the majority of this research has been conducted in the setting of developed markets in the United States or Western Europe, it can still provide a useful starting point to explore how prescription practice in peri-urban India both deviates from and conforms to these models. I will explore two theories of pharmaceutical market structure and apply them to the counter-intuitive prescribing practices observed in peri-urban Maharashtra. These prescribing practices are characterized by a dominance of more expensive branded generics, despite a low-income patient base, who ought to be price-sensitive to the cost differentials in the medications. The first theory takes into account government regulation and reimbursement policies to predict market dominance of different types of medications: generic, branded generic, and innovator drugs. The second focuses on marketing practices as the explanatory variable in shaping prescription practice.

Danzon and Furukawa have put forth a framework of physician-driven versus pharmacy-driven markets to explain the prevalence of branded generics in pharmaceutical markets.⁵⁶ They argue that differences in market share between types of pharmaceuticals—namely generic, branded generic, and innovator molecules—are due to differences in regulation and reimbursement policies between countries. Their dichotomous framework defines a pharmacy-driven market as one in which pharmacists have the ultimate say over what medication is dispensed. In these markets there is minimal to no regulation against pharmacist substitution. In fact, to the contrary, there are usually incentives for pharmacists to substitute lower priced

⁵⁶ Danzon and Furukawa (March, 2011).

generics. The payer, public or private, will remunerate pharmacists at higher levels for providing lower cost generics. In pharmacist-driven markets medications are expected to compete on price, and therefore true generics make up a large share of the market in these countries.

Physician-driven markets, on the other hand, leave the majority of medication choice in the physician's hands. Pharmacists are prohibited from deviating from what the physician has written on the prescription. Thus, as physicians have little incentive to prescribe low cost drugs, medications compete on brand quality claims rather than on price. In these markets branded generics and innovator molecules tend to dominate. Danzon and Furukawa also explore two examples of markets with less stringent regulatory and reimbursement policies than the other Organization for Economic Cooperation and Development (OECD) countries in their model. They comment on the cases of Brazil and Mexico as countries in which regulation and reimbursement policy is less reliable such that they may fall outside of the traditional framework of the model. They point to over the counter dispensing without prescription in Mexico as an example of how regulation on pharmacists to abide by written prescriptions may not play out in practice to the same extent that it does in other countries.

For these cases, Danzon and Furukawa assert that brand becomes a proxy for quality, creating a branded generic market that resembles a physician-driven market, without the same formal regulatory and reimbursement policies in place. They do not specify the actor, physician or consumer, driving these quality concerns. However, in other studies on pharmaceutical markets Danzon has emphasized the role of the consumer in quality-seeking behavior.⁵⁷ Therefore, either Danzon and Furukawa's physician-driven model or quality-driven hypothesis

⁵⁷ Danzon, P. M., Towse, A., & Mulcahy, A. W. (2011). Setting cost-effectiveness thresholds as a means to achieve appropriate drug prices in rich and poor countries. *Health Affairs*, 30(8), 1529-1538.

could be used to explain the high proportion of branded generics in the Indian pharmaceutical retail market. As India is generally considered to be a weakly institutionalized setting, the quality driven hypothesis would be the most applicable to the pharmaceutical market in the country. Thus, by Danzon and Furukawa's model, brand as a proxy for quality would be the main driving factor in shaping prescription practice and the pharmaceutical market to favor branded generics in peri-urban Maharashtra.

Another theory of counterintuitive prescribing practices comes from the literature on pharmaceutical marketing. Gönül et al. find that promotional activity and provision of free samples can influence physicians' decisions.⁵⁸ In addition, Manchanda and Honka's comprehensive review of direct-to-physician marketing in developed countries shows that the majority of studies on pharmaceutical marketing provide evidence of a significant effect of marketing on physician prescription choice.⁵⁹ Thus, pharmaceutical marketing is another framework that can be used to describe how pharmaceutical markets are shaped and how clinicians make prescription choices. The pharmaceutical market in peri-urban Maharashtra experiences a high-volume of direct-to-physician marketing. Weak regulation, currently only the self-enforced UCPMP is in place, and lack of enforcement in India combine to create an environment in which provider incentives flourish, and may have even more influence than in previously studied markets.

⁵⁸ Gönül, F. F., Carter, F., Petrova, E., & Srinivasan, K. (2001). Promotion of prescription drugs and its impact on physicians' choice behavior. *Journal of Marketing*, 65(3), 79-90.

⁵⁹ Manchanda, Puneet and Honka, Elisabeth (2005). The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review, *Yale Journal of Health Policy, Law, and Ethics*, 5(2) Article 8.

Yet, neither of these established frameworks, brand as a proxy for quality or medrep influence, can completely explain the peri-urban pharmaceutical market in Maharashtra. These frameworks do not take into account the widespread use of dispensed, not prescribed, unpackaged generic medications. The market is divided between an informal unpackaged true generic medication market and a formal market of prescription medication. The main influence on the provider's first decision between prescribing and dispensing is the characteristics of the patient's illness and the patient's expectations of the care. These influences are more individualized in nature than those explored in models based on regulatory policies or marketing structures.

Medications dispensed from clinics are not included in nation-wide statistics on the retail pharmaceutical market, as they are not technically sold, but instead included in the consultation fee of the appointment. In practice, dispensed medications are often referred to as "loose medications," and are bulk packaged and stored in jars or similar containers on shelves in providers' offices. These containers are generally either poorly marked or unlabeled. Loose medications are true generics, they are off-patent medications that have not been rebranded under a trademark name. However, as they are dispensed, not sold, these medications follow more informal channels and are thus not in direct competition with the branded generics of the formal market. This is not to say that packaged and retailed true generics do not exist. They do exist and are viable lower-cost options to branded generics. However, they are underutilized in the formal market due to the perceived quality differential with branded generics and influence of marketing on this sector.

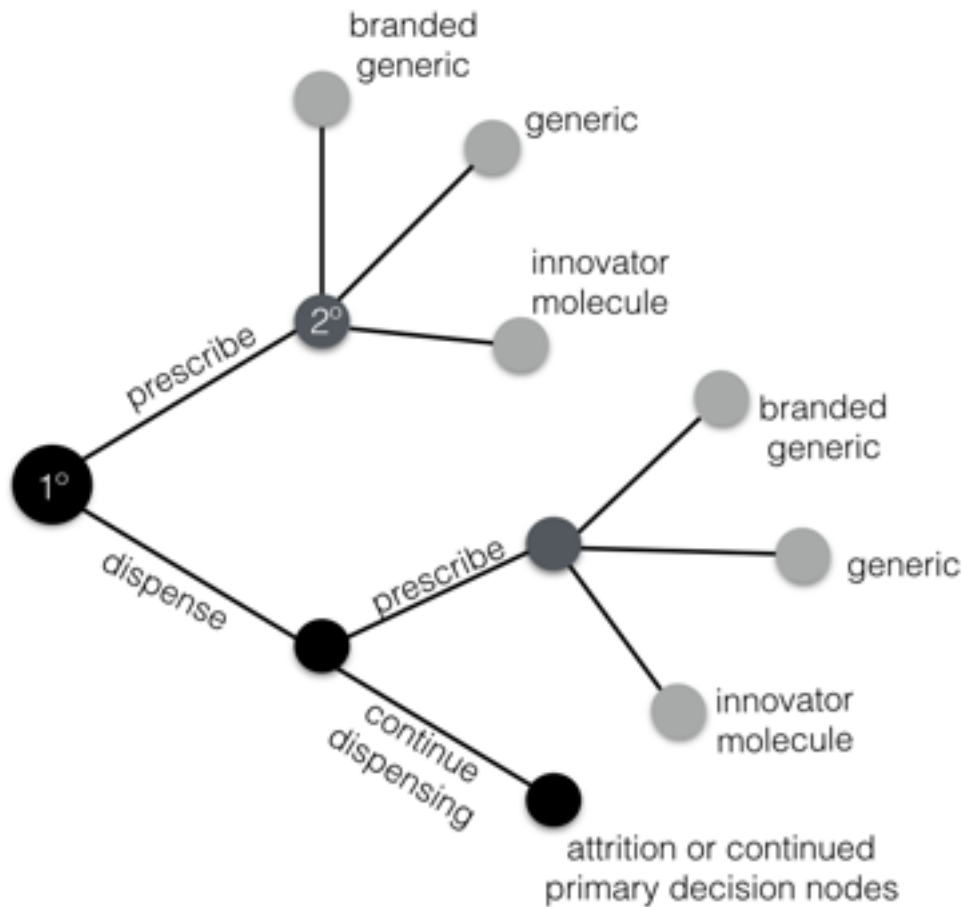


Figure 4: Decision tree for an individual provider during a clinical encounter. Primary decision nodes are in black, secondary decision nodes are shown in dark grey.

Providers then face two treatment decisions. They decide both when and what to dispense and when and what to prescribe to a given patient. The primary decision node in a caregiving encounter is whether to dispense or prescribe. The secondary decision node, after the decision to prescribe has already been made, involves what type of medication to prescribe (Fig 4). The factors influencing a provider's decision to dispense or prescribe at the first decision node are driven by characteristics of the patient and their illness course. This micro-level decision making is not encompassed in the two accepted models of prescription practice, but has a definite effect

on both the types of medications providers dispense and prescribe. Brand as a proxy for quality and medical marketing act synergistically as influences on the medications prescribed at the second decision-making node. In the case of the Maharashtrian market a new framework that takes into account the individual level influences of patients' illness and expectations is needed to elucidate the use of both dispensed and prescribed medication and how this affects the pharmaceutical market in this peri-urban setting.

The second decision node centers on the type of medication prescribed to a patient, generic, branded generic, or innovator molecule, once the decision to prescribe has been made. Current models focus on this secondary prescription-based node to predict what type of pharmaceutical market will emerge. However, I argue that the primary decision node, or the provider's decision to dispense rather than prescribe, is, in fact, just as important, if not more so, in determining market make-up and is discounted by current models. Furthermore, this primary decision node introduces a new class of entirely generic medications into the market that are ignored when looking solely at the prescription data that emerges from secondary node decisions. At the point where a provider chooses to prescribe rather than dispense, formal pharmaceutical markets in peri-urban India are primarily influenced primarily by marketing as would be predicted by Manchanda and Honda. This has led to the domination of branded generics in the Indian market. However, branded generics are only a portion of the medications patients in these areas currently receive. I will explore the factors influencing providers at the primary, dispensing, decision node and the types of medications patients receive from these decisions. Further I will validate the model of pharmaceutical marketing as an influence shaping formal markets at the secondary node, while acknowledging brand as a proxy for quality as an

important but lesser influence in these decisions. Using the case of peri-urban Maharashtra I present a new framework that takes into account the individual level influences of patients' illness and expectations in conjunction with the more systemic influence of medical marketing and brand as a proxy of quality on the pharmaceutical market in India.

Chapter 5: Care-Seeking Behavior: A Vignette

In order to illustrate what the decision making process at both primary (dispensing) and secondary (prescribing) nodes can look like in practice I will begin by presenting a prototypical care-seeking narrative. This vignette is based on reported experiences from our sample households, as well as practices commonly described by providers in our sample area. Details in this example are generalized and all names have been changed. By beginning my analysis with this short narrative I hope to emphasize the individual-level factors that influence a provider at the primary decision-making node and to demonstrate the intricacy of the interactions that go into even one care seeking encounter.

Rohit is a 30-year-old married male rickshaw driver with three children. He and his family are Muslim. He lives in a settlement on a hill slightly above the main thoroughfares of Bhiwandi. He, like many of his neighbors, is employed in the power loom industry, and he works a twelve hour shift at the looms six days a week (on Fridays power-shedding means that there is no electricity for the looms to run). He makes about 500 rupees (~\$7) a day for his twelve-hour shift and is currently the sole breadwinner for his family. Rohit has a cough and a sore throat. He goes to the chemist on his way to work and asks the chemist to give him something for his cough. A few days later, when his symptoms still have not abated, Rohit decides to go to Dr. Ansari, his local provider. Dr. Ansari is a Unani doctor who practices allopathic medicine. Dr. Ansari gives Rohit seven pills from jars in his office and sends him home with orders to return in a day. The seven pills include two doses of three and a half pills each. The first dose is to be taken immediately, followed by a second dose later that evening. Rohit does not know what these pills are, but Dr. Ansari tells him to break the white one in half and take half with each dose. Dr.

Ansari has given him amoxicillin, vitamin B, calcium, and paracetamol.⁶⁰ The white pill is the amoxicillin. The consultation fee including the medications costs Rohit 50 rupees. The next day when Rohit returns, still complaining of a sore throat, Dr. Ansari gives him another three doses of loose pills in a slightly different combination from before as well as a prescription for Ciprolet™, Dr. Reddy's brand of ciprofloxacin, a common antibiotic. Dr. Ansari offers Rohit an injection of a painkiller as well, and Rohit decides to take it. The injection is an additional 20 rupees. Dr. Ansari tells Rohit that these medications should work, but otherwise he might have to go to a lab and get his blood tested. Rohit does not want to do this, as he knows the local lab will charge him 250 rupees for this panel of testing. The follow-up appointment with Dr. Ansari is less expensive than the original appointment, but with the additional charge from the injection it ends up costing Rohit about 60 rupees.

Rohit brings the prescription to the chemist that Dr. Ansari recommended. The full course of the medication is five days but he asks the chemist if he can just have three days worth. The chemist agrees and cuts him a portion of the strip. Rohit pays 24 rupees for the three pills. After another two days his cough and sore throat go away. Rohit thinks highly of Dr. Ansari and is loyal to his practice. He had previously tried three or four providers prior to seeing Dr. Ansari. His wife has also recently started going to Dr. Ansari's clinic because she found the medications given to her by her former provider, Dr. Kamat a homeopath who practices allopathy, ineffective. If he ever did stop receiving quick relief from Dr. Ansari Rohit does not have concerns about trying out other providers in the area. Quick relief is Rohit's primary concern as his family

⁶⁰ Paracetamol is the British word for acetaminophen, the generic formulation of Tylenol.

depends on his daily wages. When Dr. Ansari's medication has been slow to work in the past Rohit has visited other providers simultaneously to try to obtain faster acting medications.

Chapter 6: The Primary Decision Node: Loose Medications and Dispensing

The majority of general practitioners (GPs) of all degree types, AYUSH and MBBS, in our sample dispensed loose medications with their clinical encounters.⁶¹ The prevalence of dispensing for GPs in peri-urban Mumbai indicates that a substantial number of the medications received and consumed by patients come from dispensing decisions as opposed to prescribing decisions. The scope of our study did not include a direct comparison of the utilization of dispensed versus prescribed medications. However, as nearly all GPs dispensed, and would often dispense prior to offering a prescription, it is probable that at least half, if not more, of the medication received by a patient in a care-seeking encounter with a GP is loose medication.

As previously described, loose medications are medications dispensed from clinics and stored in bulk, usually in poorly labeled containers. They are true generics; off-patent medications with no additional branding.⁶² Providers and their assistants, usually called compounders, generally referred to loose medications by function or appearance, for instance, a pill “for cough” or a “yellow pill.” Loose medications are part of a more informal medication market than packaged medications from chemists or pharmacies. Providers do not keep detailed records of the medications they keep or dispense, making these medications harder to regulate and track. Moreover, while chemists reported supervision and random checks by state Drugs and

⁶¹ The exceptions to this rule were specialists in allopathic medicine, MDs and Masters of Science (MS), who tended to work in larger hospitals, and who uniformly did not provide loose medications with a consultation.

⁶² They are distinct from packaged true generics which are generally carried at chemists as opposed to dispensed from clinic. While less common than storing loose medication, a significant subset of providers kept packaged medications in clinic as well and would cut pills from these packs for their patients. This practice was more common for providers in more rural areas who indicated that reaching a chemist could be a barrier for patients. Providers worried more about storing packaged medications in clinic than loose medications and indicated that storing and providing/selling too many packaged medications could lead them to lose their medical license if they were caught.

Standard Control Organizations (DSCOs), private GPs did not report these same enforcement measures for the loose medications they kept in clinic.⁶³

Loose medications remain a grey area in terms of legality and enforcement. There is no explicit language banning bulk-packaged loose medications under the Drugs and Cosmetics Act of 1940.⁶⁴ However, the law does require proper storage of medications kept in providers' clinics. In the case of loose medications these requirements are clearly violated. The medications are not kept in a climate-controlled environment and are exposed to contamination each time a provider or his compounder doles out a patient's dose. Bulk packaged loose medications are mainly produced by small, local manufacturing operations. These manufacturing plants do not face the same stringent regulations as larger multi-national corporation (MNC) manufacturing plants. Plants operated by MNCs must not only meet state and national level DSCO standards but also the standards set forth by the regulatory bodies of their export markets.

Only one manufacturer of loose medications was willing to speak with our research team. Therefore, our ability to gain information from manufacturers of loose medication themselves was limited. However, in the case of this Maharashtra-based loose medication manufacturer, there was evidence of a vacuum in the regulatory apparatus that could allow for the existence of lower quality manufacturing in this market. Furthermore, the Maharashtra DSCO inspection team, which should technically monitor all manufacturing sites, is understaffed. In 2012 only 63

⁶³ Providers did report regulation enforcement in terms of waste disposal and the amount of packaged "higher" medications they were allowed in clinic. While, not widely reported some more highly trained providers, MBBS and above, also reported occasional crackdowns on both quack and AYUSH providers in the area, meaning any provider practicing western medicine under a traditional medicine degree as well as those providers with no formal medical training.

⁶⁴ Drugs and Cosmetics Act of 1940. English Translation. Retrieved from <http://apps.who.int/medicinedocs/documents/s20107en/s20107en.pdf>

positions out of 161 total inspector positions were filled.⁶⁵ With so few resources devoted to monitoring quality and production, it remains doubtful that these small manufacturing operations undergo as intensive monitoring and evaluation of their manufacturing processes as larger corporations. If this is case, quality concerns with loose medications go beyond the poor storage methods for these pills into the composition and possible contamination from poorly regulated manufacturing. These remain pressing concerns due to the high level of dispensing in these areas that exposes patients to these loose medications of dubious quality on a semi-regular basis.

Providers use loose generics versus prescribed branded generic medications in different circumstances. Loose medications tend to be given as a first-line treatment for patients. For all of the providers we interviewed the cost of dispensed loosed medications was included in the overall cost of the consultation. Some providers charged a slight differential on a consultation fee for more “powerful,” usually packaged, medications that they stored in clinic. However, the vast majority of loose medication dispensing occurred as an integral part of the clinic visit itself. Providers indicated that if they did not dispense loose medications with a patient visit they would lose clientele. One Ayurvedic provider in Ulhasnagar articulated this sentiment, “If I just prescribe from the outside, the patient wouldn’t even ask the consultation fee, they would just leave without paying.” Loose medications are an expectation of patients when visiting private providers and an encounter is not seen as complete until medication has been exchanged. Thus, in the decision tree shown in Figure 4, providing no medication was not included as a branch.

⁶⁵ FDA Pune gets three drug inspectors. (2012, January 18). *dnaIndia*, Mumbai. Retrieved from <http://www.dnaindia.com/mumbai/report-fda-pune-gets-three-drug-inspectors-1639022>

Provider Dispensing Practices

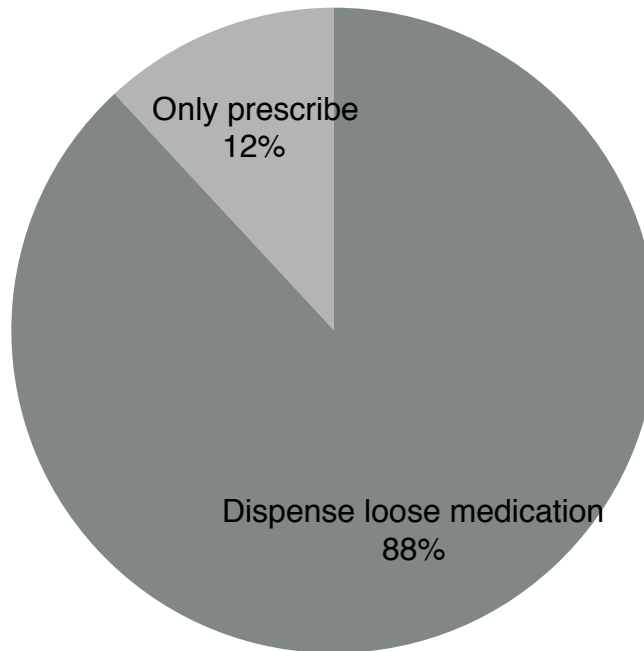


Figure 5: Provider dispensing practices in our area of study.

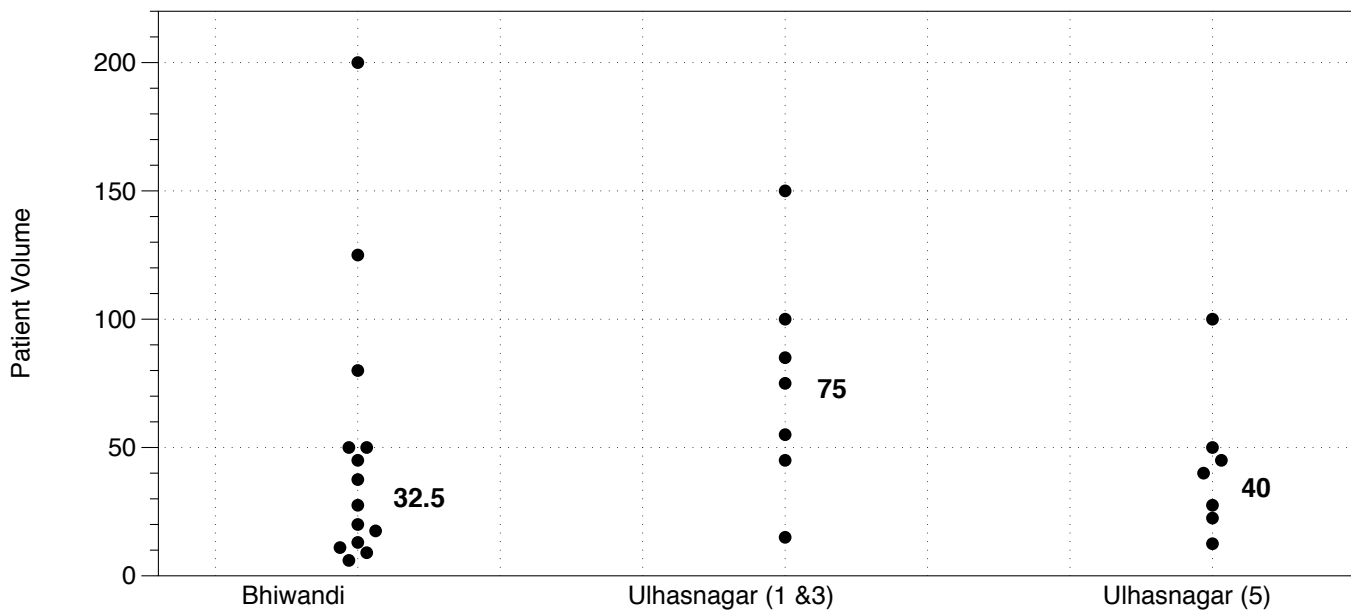


Figure 6: Private GPs in our areas of study generally saw a high volume of patients each day. This figure shows the distribution of self-reported patient visits per day in three field sites, the median number of patient visits is displayed for each site next to the distribution. When volume was reported for both high (rainy) and low season, high season volume was used.

Private GPs in our areas of study saw a high volume of patients daily (Fig. 6) and the majority of households in our sample reported a private GP as their frontline provider. Households reported an avoidance of public facilities for all but very expensive and major medical events, for instance giving birth. While there were a few providers (see Fig. 5) who did not dispense loose medication, the majority of private GPs in these peri-urban areas conformed to patient expectations of dispensing.⁶⁶ Unlike private sector GPs both public sector care providers as well as more specialized private providers eschewed the practice of dispensing from clinic. Thirty-seven of the forty-two private providers we interviewed reported keeping medications in clinic to dispense with consultations (Fig. 5). Of the five that did not, three were specialists. While specialists do play an important role in medication prescription at the secondary decision node, they are primarily accessed by higher income patients for specific conditions. Thus, for all practical purposes, specialists are irrelevant to the discussion of factors influencing loose medication provision.⁶⁷

As GPs act as primary care providers for the large low-income populations in peri-urban areas, they are most directly involved in shaping what medications are available to this population. Households were generally confused by the question of whether receiving loose medication in a care encounter was important to them, as many genuinely had not had a care-seeking experience where medication was not offered to them. The vast majority of GPs in our

⁶⁶ We did not interview any public sector GPs, however suppliers and households informed us that loose medications were not given in the public care context.

⁶⁷ The two remaining providers in our sample who did not dispense loose medications also had unique characteristics. One was from Bihar, where he indicated that the norms of dispensing he learned in his training were different. He claimed to have earned his MBBS degree in Bihar where he reported that dispensing from clinic was rare. He therefore continued to practice the way he had learned medicine, without dispensing medicines from clinic. The final provider who did not dispense from clinic was an MBBS provider who had decided that the quality of the loose medications was too low and the practice of dispensing also made his patient-base “too dependent” on him.

sample did dispense indicating that this practice is a community norm, and is expected by patients in care-seeking encounters.

Beyond community norms, the dispensing of loose medication is influenced by two primary factors. To start with loose medication serves as a proxy method of diagnosis. Providers dispense mainly anti-symptomatic⁶⁸ loose medications in a first encounter as a way to narrow down their differential diagnosis. Self-limiting illnesses, such as the common cold or stomach discomfort, will resolve with time, although they may be eased by anti-symptomatic treatment. However, more serious and systematic conditions will persist. By this logic, a patient presenting with a fever who continues to feel ill after being treated with mainly anti-symptomatic loose medication is more likely to have a serious infection like typhoid, dengue or malaria.

Patient resistance to diagnostic testing further encourages this practice. When asked, most providers described their treatment process as a day or two of treatment with loose medications followed by diagnostic testing. The vast majority also reported that patient compliance with ordered lab testing was spotty. Providers complained of patient avoidance of what are seen as costly and unnecessary tests. Some providers indicated that patients responded to requests to get diagnostic testing by switching providers instead of accessing the appropriate testing. Diagnostic testing is more expensive than the average consultation price for a general practitioner. Of the GPs we interviewed the average price across 27 BAMS, BUMS, BHMS and MBBS providers was 47.5 rupees a consult, including loose medications (Fig. 7).⁶⁹ Diagnostic testing, on the other hand, usually cost upwards of 150-200 rupees. This can equate to nearly a day's income or more

⁶⁸ I use the term anti-symptomatic to refer to medications that target the symptoms of illness: fever, cough, pain etc without targeting the root cause of the malady such as a bacteria, virus or parasite.

⁶⁹ This price does not include injections which added, on average, about 15 rupees to the consultation fee.

for the households we interviewed in Ulhasnagar and Bhiwandi. Patients also view the expenditure of time and effort to access the facilities and follow up with results as undesirable. One of our interviewees, an Ayurvedic provider described how he maintained his patient base and reputation: he both gave out free and reduced cost medication to low-income patients and “diagnosed without investigation,” based on his examination alone. He viewed his ability to suggest a treatment plan without diagnostic testing as one of his most important qualifications in keeping patients satisfied.

The second important factor that influences a provider’s decision to dispense loose medication is the ability of loose medication to provide a tangible value to the clinical encounter that may not otherwise be apparent to patients when there is no physical exchange of goods. This is evidenced by the way patients assign worth to the loose medications they receive. Providers report that patients see higher volumes of medication given with each consultation as a measurable proxy for quality and value. In this sense, loose medications can be seen as a solution to the problem of asymmetric information in healthcare markets. While patients still do not have the full ability to evaluate the quality of care they are receiving, they may use the medication they are given to as a quantifiable metric to assess provider effort and skill. Provider perceptions of the way patients measure value in clinical practice can also drive provider use of loose medications.

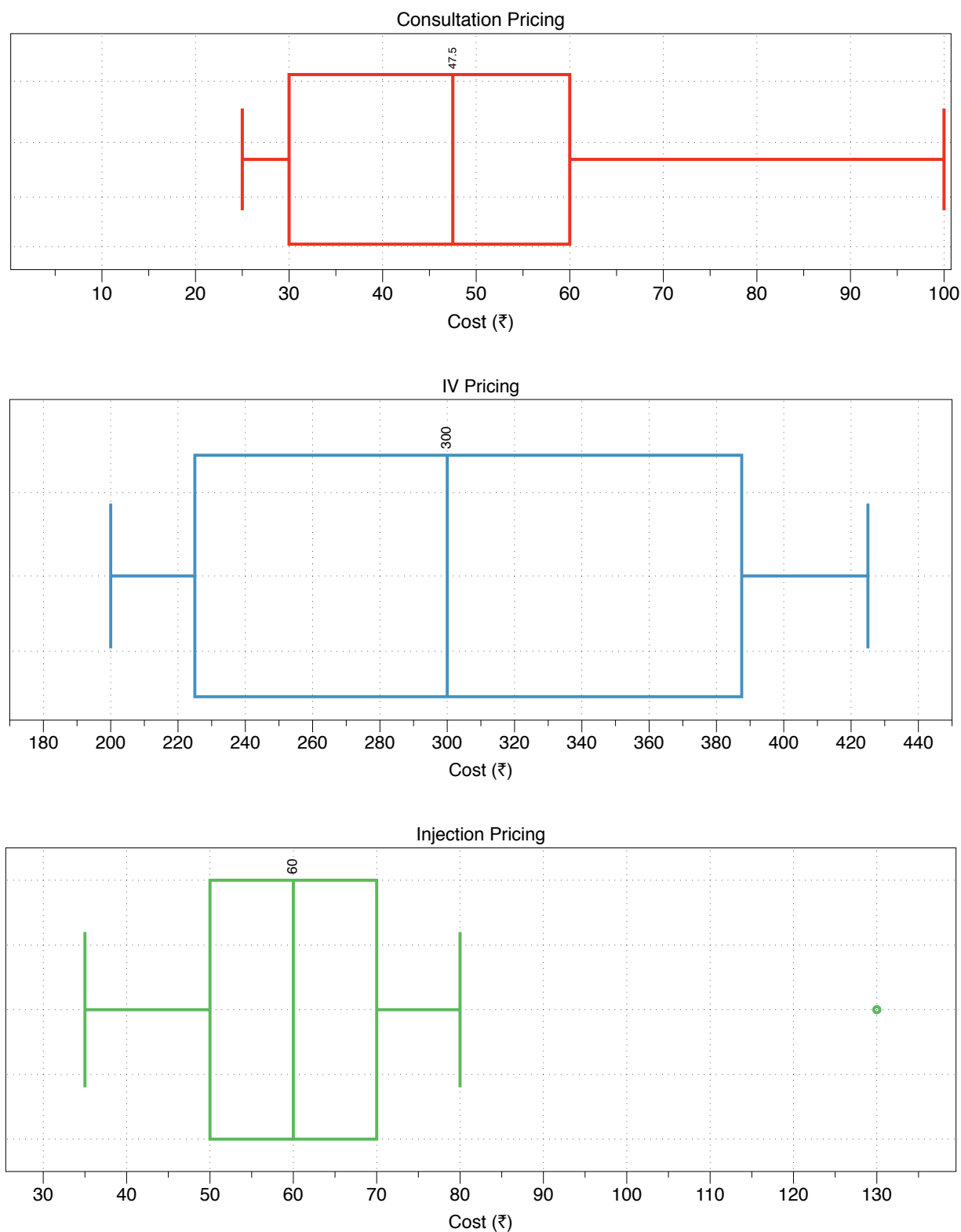


Figure 7: Pricing of services at providers. Prices in rupees, median cost is indicated. When a range of prices was given the average price of the range was used. For a range of between 35-45 rupees 40 rupee was used e.g.

Patient use of tangible goods and services as proxies for value has previously been documented in studies of patient preference for injections in peri-urban India.^{70,71,72} As with injections, patients perceive a value and benefit to receiving loose medications. However, there are economic disincentives to providers to dispense large volumes of loose medications. An incentive structure of “up-charging” exists for injections, which can also be bulk-purchased at low cost by the provider, and tend to be in high demand by patients. Providers, however, do not gain the same up-charging benefit from providing loose medications. While each injection will cost a patient progressively more, the benefit of being able to charge a higher consultation fee does not scale with the volume of loose medication dispensed to a given patient. That is, providers do not raise their consultation fee based on the number of medications dispensed during a particular patient encounter. One would expect this lack of scalability to actually disincentivize the provision of large volumes of loose medication, as providers reduce their marginal gains by giving more medication under a constant consultation fee. Providers described the provision of loose medication to be a near inviolable patient expectation, and not an add on. Following this logic, the consultation fee a provider charges, which includes several doses of loose medication, cannot be viewed as a separable charge from the cost of the visit itself. The economic incentives present for providers in supplying services such as injections or IVs therefore do not exist in the same way for the dispensing of loose medications. It was mainly providers who reported patient preference for high volumes of loose medication versus

⁷⁰ Rajasekaran, M., Sivagnanam, G., Thirumalaikolundusubramanian, P., Namasivayam, K., & Ravindranath, C. (2003). Injection practices in Southern part of India. *Public Health*, 117(3), 208–213.

⁷¹ Anand, K., Pandav, C. S., Kapoor, S. K., & Undergraduate Study Team. (2001). Injection use in a village in north India. *The National Medical Journal of India*, 14(3), 143–144.

⁷² Kotwal A, Priya R, Thakur R, Gupta V, Kotwal J, Seth T. (2004) Injection practices in a metropolis of North India: Perceptions, determinants and issues of safety. *Indian J Med Sci*. 58(3), 34-44.

households themselves. This leads to the critical question of whether providers might, in fact, dispense high volumes of medication for personal gain, rather than actual patient demand. However, the economic disincentives to providing more loose medication indicate that this practice is likely patient-driven as providers do not stand to benefit from over-provision.

Perceived patient pressure to give out large volumes of loose medications with a consult meant that providers also reported giving vitamins in their pill packets. Providers reported engaging in this practice both from a desire to “pad out” the pill packages given to patients as well as for clinical reasons such as treating malnutrition in a low-income patient base. On the extreme end of pill “padding”, one provider told our team that the loose medications he provided were “sugar pills” (placebos) solely meant to reassure patients. No other providers in our sample reported the same extreme of placebo care, but the use of loose medications as palliatives for patients’ worries versus physical ailments remains salient even in less dramatic cases.

The use of loose medication as a proxy for diagnosis and to serve as a quality indicator for patients does not mean that the loose medications commonly dispensed are solely anti-symptomatic treatments. Every provider who was willing to report which medications they kept in clinic, or for whom we could identify the medications in clinic, kept common painkillers, diclophenac/paracetamol. However, the majority also kept what they described as “light” antibiotics. “Light” was a fluid term used to refer to non-combination second-generation antibiotics like amoxicillin. Therefore, loose medications, while used in part as an interim measure to wait out self-resolving illnesses, also often included curative medications such as antibiotics as well. A small subset of the providers who kept loose medications (5%) kept antimalarials in clinic. About a third of providers interviewed also kept advanced generation

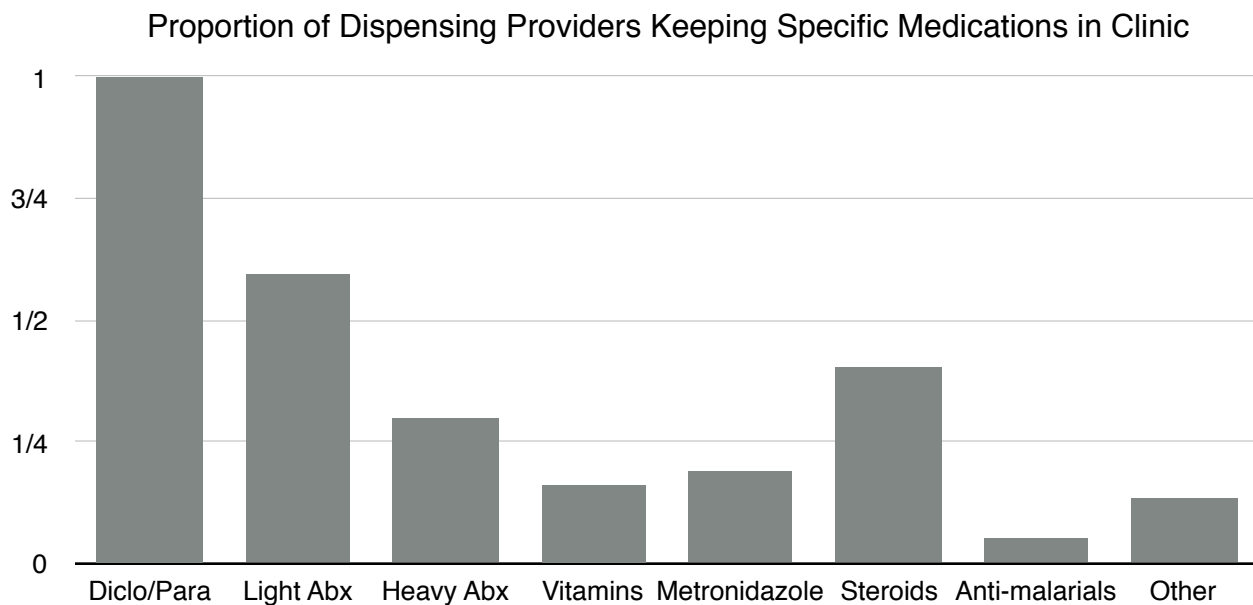


Figure 8: Proportion of dispensing providers who kept specific medications in clinic. Other category includes albendazole, antivirals, omeprazole, and antacids. The steroids category is primarily composed of dexamethasone. When the type of antibiotic kept in clinic was not specified light antibiotic was assigned as the default. Amoxicillin was the most commonly reported “light” antibiotic. Ciprofloxacin, cefixime, anofloxacin, and azithromycin were the most commonly reported “heavy” antibiotics. As not all providers were willing to discuss the medications they kept in clinic in great detail these proportions are most likely underestimates of the true proportions of providers keeping certain types of medications and supplements in clinic.

antibiotics like ciprofloxacin and azithromycin in clinic. Providers also commonly kept dexamethasone, a “light” steroid in loose form in clinic. While the presence of dexamethasone in clinic was common, it remains uncertain how often providers actually included this medication when dispensing. Many of the same providers who either reported or were observed keeping dexamethasone in clinic also displayed some knowledge of specific uses for steroids as well as an understanding of the dangerous side effects of overuse. The use of curative medications along with anti-symptomatic introduces a third possible factor in provider a provider’s decision to dispense. Delayed prescription, in favor of dispensing, could be seen as a cost-saving measure for patients with more minor illnesses. By waiting to prescribe from chemists, providers allow

access to the loose medicines they dispense, without the same cost of filling a prescription at the chemist.

Patients do not differentiate readily between the effects of loose and prescribed medications. We found that providers generally dispensed loose medications for at least one day before co-prescribing. However, providers also sometimes did prescribe concurrently to dispensing loose medications. Due to this practice, all of the households we interviewed reported that they were unable to see a difference in efficacy between loose medications they received in clinic and the medications they were prescribed at pharmacies, as they often took both simultaneously or in quick succession. As they saw it, there was no way for them to discern which medication(s) were contributing to their decrease in symptoms if they tended to take both types within a short time span. Patients do not view loose medications as a be all end all curative measure, but they are an important and expected part of a clinician visit. Patient expectations and demands, as perceived by the provider, drive the dispensing of loose medication, and patients themselves also benefit from the low-cost access to medication, albeit of questionable quality, that dispensing provides. Dispensed medications make up a significant portion of medication accessed by low-income populations in the peri-urban Mumbai area.

None of these demand-driven factors are included in formal models of the pharmaceutical market in peri-urban India. Established models do not account for the existence of less formal pathways of medication provision such as the clinic-based dispensing seen in peri-urban Maharashtra. However, this pathway is clearly important in shaping the that patients', especially low-income patients', access to medications. Loose medications are less costly for these consumers, as they are included in the consultation fee of the visit. In some sense, while the

formal networks of prescription medications in these areas form a market dominated by branded generics, loose medications have taken on a role akin to that of true generic medications in formal markets. They are inexpensive for both the provider and the consumer and broaden access to medication by eliminating some of the cost-limitations of prescribed medication. The quality concerns with loose medication do complicate its use, as will be discussed further in the concluding section.

Chapter 7: The Secondary Decision Node: Prescribed Medication

Factors that influence the prescription node of provider decision-making play a significant role in determining the make up of the formal medication market. Once a provider has decided to prescribe, generally after a return visit by a patient, both brand as a proxy for quality and pharmaceutical marketing can influence their decision to prescribe a branded generic. While, the two models are presented as distinct in the literature, pharmaceutical marketing interacts with the idea of brand as a proxy for quality, as the perceived superior quality of a given brand is reinforced by targeted marketing.

The timing of prescription writing in our area of study differed from that of dispensing. Medications tended to be prescribed later in the illness course than loose medications were dispensed, and prescriptions were nearly uniformly for branded generics. The majority of providers who both dispensed loose medications and prescribed from chemists viewed the medications they prescribed from the chemist as stronger than those they dispensed (Fig. 6). They therefore preferentially prescribed versus dispensed medications when they viewed the illness as longer lasting and more serious. This practice is the complement of using loose medication as a proxy diagnostic tool for potentially self-resolving illnesses. There was, however, significant heterogeneity in the stage of illness at which providers prescribed. Many providers described a system by which they would begin by dispensing from the clinic, but generally provided only sufficient dosage for one or two days of treatment, and encouraged patients to return for follow-up care after they finished this allotment. If patients continued to complain of illness after this treatment, they would then prescribe from an outside chemist or eventually order diagnostic testing. In practice, however, providers were observed to often

prescribe and dispense simultaneously. This is in part due to fact that follow-up patients still expect to be given loose medications even if they are concurrently prescribed medication from a chemist.

GPs nearly uniformly prescribed branded generics by their brand or company name on their written prescriptions for patients. As described previously, branded generics are medications which are off patent and are therefore usually made by a variety of manufacturers, but have been re-trademarked and are marketed under different brand names. Branded generics can also include new dosages of existing medications, for instance a 500mg version of a medicine that was previously manufactured at a 250mg dose. The molecule in the formulations remains the same, even if the dosage is modified. GPs associated the term “generic” solely with the loose medications they stocked in clinic, and not with forms of packaged true generics available at chemists or public hospitals, indicating how rarely these packaged true generic medications were prescribed. Branded generics are sold at higher prices than their true generic counterparts.

In our interviews a loose medication manufacturer estimated the price differential between branded generics at a pharmacy and loose medications to be about 100 times different. A package of ten paracetamol at a pharmacy would cost sixteen rupees whereas a bag of 1000 paracetamol tablets sold to a GP would cost the same amount. True generics sold at chemist shops are also less expensive than branded generics, although the differential is less staggering than between branded generics and loose medications. It is difficult to estimate the actual price difference between packaged true generics and branded generics for two reasons. The first is simply that true generics are currently rarely sold at chemist shops. Secondly, the registered

maximum retail price (MRP) for true generics is not indicative of the price for which these medications are usually sold in practice. The MRP of true generics tends to be about 10% less than the cost of branded generics, although there is significant variation on branded generic prices (see Table 2). Typically, a chemist makes about a 20% profit margin on a given branded generic. However, the cost of purchase for true generics is significantly lower for chemists. Thus, in contrast, chemists can make up to an 80% profit margin on the the sale of true generics at MRP. Many of the chemists we spoke with reported selling true generics at prices below the MRP value in order to incentivize sales. As the profit margin is so high for the sale of true generics, chemists were able to sell at prices significantly below MRP and still make a good margin on the medication. Therefore, in practice, the sales price of true generics is even lower than their listed MRP. This price differential makes true generics a more obvious choice for patients at the prescription decision node, and one would expect provider decisions here to reflect the price-constraints of patients in these areas. Yet as previously noted, this is not what is seen in practice. Instead, other factors besides conventional economic logic must be at work at this node.

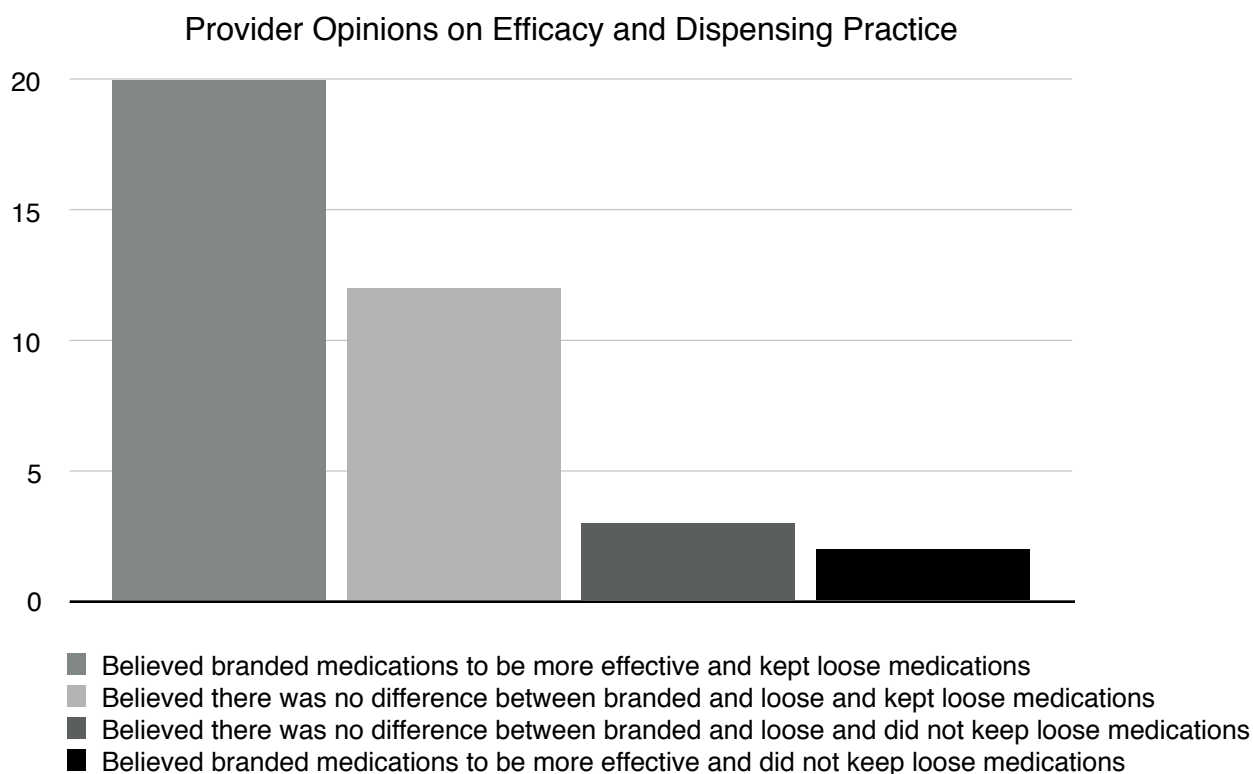


Figure 9: Provider opinions on the difference in efficacy between loose and prescribed (branded) medication by provider dispensing practices.

Trade Name	Bactoquin	Ceplox	C-Od	Ciplox*	Ciprind	Ciprocore	Ciprocure	Penquin	Quinotab	Strox	Cifran
Manufacturer	Aristo Pharma	Mimec Pharma	Glaxo	Cipla	Indoco Remedies	Core Healthcare	Radicura Pharmaceuticals	Hindustan Antibiotics	Glaxo	Dabur Pharmaceuticals	Ranbaxy
Unit	500 mg	250 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg
Type	Capsule/ Tablet	Capsule/ Tablet	Capsule / Tablet	Capsule / Tablet	Capsule/ Tablet	Capsule/ Tablet	Capsule/ Tablet	Capsule/ Tablet	Capsule/ Tablet	Capsule/ Tablet	Capsule/ Tablet
Quantity	10	10	5	5	10	10	10	10	4	10	10
Price (Rupees)	38.04	25	35	56.14	36	42.5	39	29.7	30.34	39	98.60
Average Price for 10 Capsules of 500mg	53.237										
Average Price Glaxo, Cipla, Ranbaxy	85.39										

Table 2: Prices of branded generic versions of ciprofloxacin, a common antibiotic. Glaxo, Cipla, and Ranbaxy are three of the most commonly prescribed brands, and as better known MNCs the prices of their formulations tend to be higher on average than other brands.

Even making a decision on what branded medication to prescribe can be a complex choice for providers. On average in India each drug class contains twenty-six branded generics sold in the retail market.⁷³ For the most common medications prescribed this number can be even higher. For instance, Medindia⁷⁴ lists 43 different brands of ciprofloxacin, a common antibiotic. Every prescription a general practitioner writes requires a decision on which brand to prescribe. Providers generally reported higher trust in multinational companies, citing greater faith in the quality of these companies' medications. There was significant variation in brands mentioned by providers, but larger multinational companies such as Ranbaxy, Cipla, and Lupin were most commonly mentioned.⁷⁵ While providers, on the whole, do value branded medication as a more powerful curative measure for more complicated illnesses, brand as a proxy for quality fails to explain how providers choose between the wide variety of branded medications available for prescription. Though providers tended to favor large MNCs more than smaller companies in their prescribing practices, many of these same MNCs have been implicated in contamination scandals. These scandals appear more often in the news than reports on smaller national companies, as the larger MNCs face additional scrutiny and reporting from international organizations. If providers based their prescribing decisions on solely on publicly available information, then favoring MNCs would not logically support brand serving as a proxy for quality. The influence of medical representatives in the system, on the other hand, plays a significant role in elevating certain brands for providers. While providers were nearly evenly split in their reported trust of information provided by medreps, medreps are clearly important

⁷³ Danzon, P. M., Towse, A., & Mulcahy, A. W. (2011).

⁷⁴ MedIndia is one of the first Indian healthcare online informational sites for doctors and consumers.

⁷⁵ Sun Pharma, Aristo Pharmaceuticals, Leeford Pharmaceuticals, Glaxo pharmaceuticals, Dr. Reddy's, and Sandoz pharmaceuticals were also brands that were mentioned by more than one provider.

players in motivating brand as a proxy for quality, and therefore prescription of branded generics in the peri-urban pharmaceutical market.⁷⁶ Furthermore providers may underreport their trust of medrep information to avoid admitting to being influenced by medical marketing.

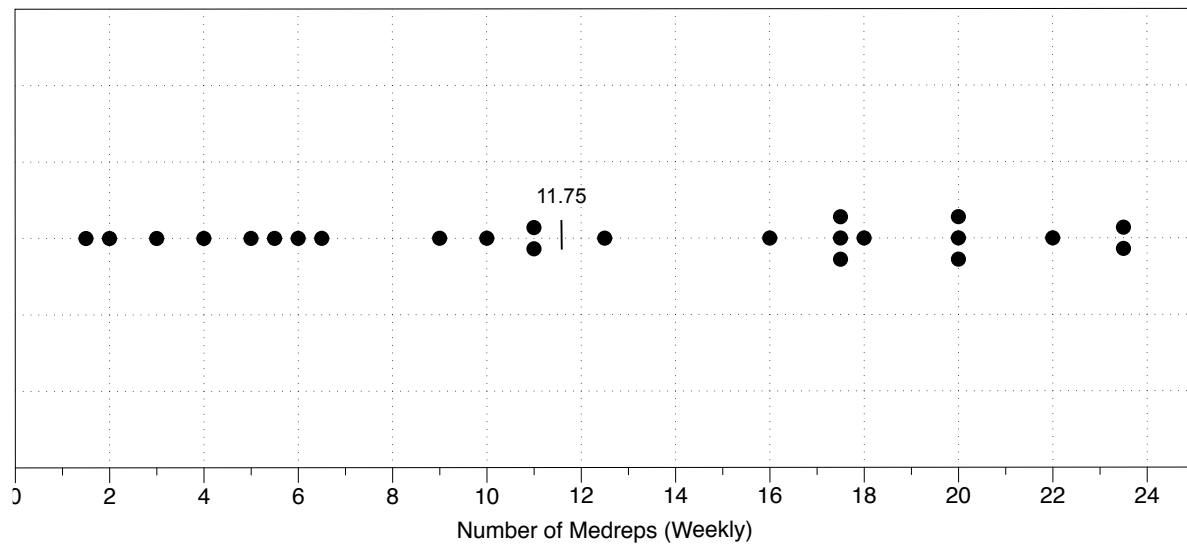


Figure 10: Number of weekly medrep visits reported by providers. The providers on the lower end of the spectrum tended to be more rural and therefore less accessible to medreps. The median number of medrep visits per week is noted.

The important role medreps play at the prescription decision node is further demonstrated by the sheer volume of medreps in the peri-urban pharmaceutical market in India. Even smaller, national firms have representatives who regularly visit providers to share information about new products. One major pharmaceutical company described the medrep market as “saturated” and many providers we spoke with would set aside a specific day of the week when they would see medreps to avoid being overrun on a daily basis. One provider even joked that he saw more

⁷⁶ 47% of providers reported that they did not trust medrep information in general, or at least not as much as other sources such as the literature. 41% reported they did generally trust medrep information. 11% reported that they trusted medrep information sometimes, mostly to hear about new medications but felt that medreps did not ever give any information about side effects of medications.

medreps than patients some days. Due in part to the sheer volume of interactions providers have with medreps, these meetings were observed to be short in duration, generally between 1-2 minutes. We observed several of these pitches, primarily of a large multinational corporation that allowed our team to shadow its marketing team in the field. The medrep/provider interactions we observed consisted generally of short, memorized pitches stating the name of the products and the primary indication of the medications the medrep was marketing. Perhaps more importantly, medreps left samples and other informational materials with providers.

The prescription of branded generics is also not checked via substitution of true generics at the chemist. To be profit-maximizing chemists should support the sale of true generics, rather than branded generics, as the potential for their price mark-up on true generics is greater. However, the ability of chemists to substitute in true generics for prescriptions is checked by the prescribing provider. Providers enforce their decision of brand by preventing substitution at the chemist. Substitution, or the practice of swapping out a prescribed medication for either another brand or a true generic, is illegal in India.⁷⁷ However, chemists reported that it was a fear of the provider, and the subsequent inconvenience to the patient that prevented them from substituting on written prescriptions.⁷⁸ Chemists reported that providers would ask patients to return to the clinic after filling a prescription so that the provider could ensure they had been given the right medication, including the exact brand that had been written on the prescription. This check was strong enough in practice that chemists rarely substituted in true generics for a prescription, even

⁷⁷ Singal, G. L., Nanda, A., & Kotwani, A. (2011). A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacturer in India. *Indian Journal of Pharmacology*, 43(2), 131-136.

⁷⁸ This is in contrast to other legal concerns for which chemists were likely to report a fear of credible enforcement. For instance, chemists reported DSCO/FDA enforced checks of sales records to ensure chemists were not giving scheduled medications over-the-counter.

if cost was a limiting factor for the patient. They further indicated that patients themselves are not necessarily interested in substituting for a less expensive generic, and place a high degree of trust in the provider and their specific prescription.

The interactions of medreps with both chemists and providers reinforced the provider-side check on chemist substitution. Medreps used data they collected from chemist written records to inform providers as to which chemists stocked medications of a certain brand. Providers were discouraged from sending patients to chemists who did not carry a particular medrep's brand. They were instructed to refer their patients elsewhere for medication to avoid substitution on the prescription by the chemist. Chemists in turn expressed that "doctors prescribe [branded medication] because there is an understanding between the doctor and the medical representative," and that "a doctor is only writing a particular brand, and he doesn't really care about the price for the patient."⁷⁹

Both chemists and patients stand to benefit monetarily from the lower cost of true generics compared to their branded generic counterparts. Pharmaceutical marketing influences providers' decision making at the prescription node, the secondary node in Figure 4, and blocking substitution means that this decision node is not alterable by other players in the system, namely chemists. Pharmaceutical representatives in these areas not only give providers information to more effectively block chemist level substitution of less expensive medication,

⁷⁹ This opinion was not universally held. Some chemists seemed to believe that there was a difference in the quality brands and different providers prescribed different brands based on their skill and knowledge level. These chemists believed that better educated, more skilled, generally MBBS, providers tended to prescribe "better" brands. This subset of chemists derived further evidence from their observation that more educated providers prescribed the full course of a medication, while their "less educated" counterparts might only advise filling a prescription for one or two pills.

but they also put pressure on the provider to prescribe branded generics instead of less costly true generic medications.

Providers reported that materials and samples given by medreps were influential in their decision to prescribe a medication or not. A subset reported using the samples on patients to determine whether or not a medication was actually of high quality through quasi-experimental methods. Inter-personal relationships and non-medical incentives were mentioned less frequently by providers, but were clearly an influential aspect of the interactions between providers and medical representatives. In fact, medreps reported these relationships as one of the most important aspects of their marketing.

Every medrep we spoke with, regardless of their company affiliation, followed a similar scheme of provider interaction. They described a strategy of mapping the market prior to designating providers to a certain category. In new areas they would use chemists' records of prescriptions to determine which providers were already brand loyal to a different company versus those that remained more susceptible to marketing. These "susceptible" providers were then sorted by patient population and prescription volume, with providers with larger patient bases and prescription volumes seen as more desirable marketing targets. Providers were classified into A, B, C, and D ratings, with classification A corresponding to providers with the largest patient populations who were most likely to prescribe the marketed medication. Degree type did not factor into the ranking system medreps used for providers. Thus for medreps targeting GPs, usually with antibiotics, antispasmodics, cough/cold medication and other everyday medications, MBBS providers were not prioritized over Ayurvedic, Unani, and

Homeopathic providers.⁸⁰ Once categorized, providers are visited in a preferential manner by classification. The number of visits in a given time period varied by company, but a generalized schema would be: category A providers being visited weekly while category B and C providers might only be visited every fortnight. In this hypothetical schema category D providers would be visited only rarely, if at all.

These visits were important to medreps to build interpersonal relationships with providers. Medreps described these relationships as the main way they were able to work with providers to have their medications prescribed. Medreps who switched companies reported that their relationships with providers would often transcend these career changes, thus they could bring certain providers along with them in the brand switch. In addition to friendships, medreps also used more tangible incentives to win provider loyalty. These ranged from small gifts including rice cookers, towels and other household items, to sponsored trips and even direct cash incentives. The practice of receiving gifts was widely reported among providers, although a good portion denied accepting gifts in order to avoid medrep influence. Pharmaceutical company sponsored conferences and continuing medical education seminars (CMEs) were reported by both medreps and providers as common practice. Providers are invited to these events to learn about a condition or new technology or medication marketed by a pharmaceutical company which fund the event.⁸¹ Finally, a subset of providers reported that there were arrangements by which providers could receive a direct cut of the sales of certain medications if they successfully

⁸⁰ Medreps did make a distinction between specialists and GPs. Specialists were usually targeted by different medreps than their GP counterparts, as the types of medications and technologies being marketed were different for each specialty.

⁸¹ A larger multinational firm reported to our team that they would sponsor groups of specialists on trips to international conferences. However, these more costly trips were reserved for specialists and not GPs, as specialists were more likely to be prescribing high cost medications that the company was interested in promoting.

up-prescribed. It is unclear how pervasive this practice is. Our interviews indicate it may be limited to more experienced and well established providers with whom a medrep may already have significant rapport. One newer Unani provider in the area stated that she currently did not receive these types of kickbacks, but she hoped that once her practice had grown more established she would be offered this same kind of compensation that she knew other providers in the area received. There was some disagreement over whether it was smaller or larger branded generic companies who were offering more extreme gifts and incentives. Smaller companies indicated that they did not have the resources to offer as appealing incentives as larger companies, but larger companies alleged that it was smaller companies who faced less regulation and therefore could offer larger monetary gifts.

As described above the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) was implemented nationwide as a self-enforced industry code of conduct in 2015. The UCPMP clarifies the ban on gift giving and incentives from the pharmaceutical industry. However as the UCPMP entails strictly voluntary compliance it is unclear whether it has had an effect on medical marketing practices and incentives. Thus, as legislation implementing further mandatory restrictions pends, medrep practices aimed at incentivizing providers remain in a murky legal grey area. Illegal or not, in the summer of 2015 when we conducted our field research, medreps were still relying on incentives and gifts to build rapport with providers in an attempt to increase brand prescriptions.

The high cost of prescribed medication can be burdensome to patients. When prescribed medication, many patients seek out cost saving measures at the chemist including cut strip practice. Cut strip practice occurs when patients request less than the standard course of

medication from the chemist such that they only have to pay for the number of pills purchased, instead of the entire course. Chemists generally fulfill requests for cut strips, although some reported reluctance due to fear that they might not be able to sell the rest of the strip after it had been cut. This practice is further encouraged by providers who often specify a pill number less than the full course of a medication on their prescription. Providers expressed regret at prescribing less than what they knew to be the “proper” course, but felt limited by their patients’ income, and believed that getting some treatment was better than none for patients. As one long time Ayurvedic provider summarized his predicament, “every patient should take 7 days medicine, I give 2-3 days and that is wrong but what can I do there is nothing in my hand.” There was also a widespread perception that patients stop taking their medications after their symptoms abate in any case, thus, not prescribing a full course might not be so dissimilar to a patient purchasing a full course but stopping once they no longer felt ill.

Households also reported occasionally using over-the-counter medication from the chemist for convenience. Cost of medication directly from the chemist can also be minimized, compared to when a medical provider’s prescription is used. As substitution for true generics is technically illegal, and in practice is heavily disincentivized by both providers and medreps, chemists report that it is through OTC sales that they are able to move true generics. These sales maximize chemist profit margins, but also minimize price to patient. This is in contrast to medications prescribed by providers which, as stated above, are nearly always higher priced than branded generics. One true generic wholesaler we spoke with indicated that a large portion of his job involved convincing chemists to stock his medications by showing them how their profit margins could grow through over-the-counter use of true generics. Patients seeking medication at

the chemist have little to no brand loyalty, and are one of the only reported sales outlets for unbranded generics in the private sector. Thus, on the patient side, brand as a proxy for quality has little bearing on the medications patients seek out. In fact, in direct to chemist care-seeking interactions, where neither a provider or medrep is involved, chemists reported one of the few instances where they were able to sell true generic stock. This emphasizes the role of the medrep and pharmaceutical marketing in shaping the medications patients are able to access through a provider's prescription in a typical interaction. Branded generics are dominant in this framework not because of a patient desire of brand reassurance, but because of a provider mandated brand adherence that is more costly to patients without clear added benefits. Furthermore, branded generics remain dominant in the formal pharmaceutical sector overall as the majority of households in our sample did not view OTC self-medication as a viable alternative to seeking the advice and care of a private GP.

The prescription node of provider decision-making determines the formal pharmaceutical market make-up in peri-urban India. While providers have the option to choose between innovator, branded generic, and true generic medications at this node, currently branded generics dominate in market share. Medrep influence, which in turn motivates brand as a proxy for quality, is integral in shaping the decisions providers make at this node.⁸² The medical representative is an under characterized player in developing country pharmaceutical markets, yet in the case of peri-urban India he plays a crucial role in shaping what medications patients access through the formal sector. This is compounded by the fact that chemists are unable to substitute on provider prescriptions so that there is no check on this driver of the pharmaceutical

⁸² The prohibitively high cost of innovator molecules means that these medications are not marketed to private sector GPs who mainly serve a low-income population.

market. Despite their prevalence, branded generics are still cost-prohibitive to patients. This is evident not only in the higher MRP of branded generics, but in the cost-saving measures, such as cut strip practice, that households utilize to mitigate price.

Chapter 8: Concluding Thoughts

The formal pharmaceutical market in India is made up primarily of branded generics. This has led to the false perception that these are the medications both primarily accessed and preferred by the Indian patient. I have argued against this perception by characterizing the factors at the formal prescribing node that influence the provider, not the patient, towards branded generics. Further, I have explored the informal channels of loose medication distribution in peri-urban Maharashtra to demonstrate how these loose medications make up a significant portion of the medication accessed by patients in these areas. This loose medication informal sector is completely neglected by current models of pharmaceutical market make-up. Although these models prove more predictive at the formal prescription decision-making node, they have rarely been applied to a developing country context. I apply the models of brand as a proxy for quality and pharmaceutical marketing to show how they interact to drive prescription of branded generics in peri-urban India. In isolation, however, the theory of brand as a proxy for quality is a dangerous one, as it discounts the role of pharmaceutical marketing in creating the paradigm of certain brands as higher quality than other options. I have shown that marketing plays a significant role in promoting brand as a proxy for quality and has a substantial influence on provider decision-making at the prescription node. The role of marketing in a less developed context, such as peri-urban India, has previously been under-characterized in the literature.

The factors that influence both the dispensing and the prescription nodes of provider choice shape the current make-up of the Indian pharmaceutical market. The complexity of these factors has been underemphasized in previous models, which have also failed to account for the dispensing channels that make up a significant share of medication provision in peri-

urban areas. Neither channel is ideal in providing access to medication for patients. Informal dispensing channels come with troubling quality concerns, while, currently, formal prescription channels are characterized by high priced branded generics. It is important to consider the factors that have led the market to be shaped in this way as one considers ways to improve medication access for low-income patients in peri-urban areas of India. Both the perceived demand-side factors that providers report as driving their dispensing practices, and the medical marketing propagating brand as a proxy for quality will need to be addressed in encouraging the use of low priced, but better regulated, true generics.

The dominance of branded generics in the pharmaceutical market, has a real negative effect on low-income patients in peri-urban Maharashtra who, in the majority, pay for healthcare out-of-pocket. Informal channels of medication provision through provider-level dispensing yield an alternative route to obtain less expensive medications included in the consultation. GPs also utilize them as a tool to proxy diagnosis, which can also help patients avoid costly diagnostic testing. However, these loose medications remain in a grey area of regulation, casting their quality into doubt. Patients expect, and depend on, private GPs providing loose true generics with consultation. Yet, informal channels of loose medication distribution are not a palliative to the high cost of branded generic prescriptions, instead they add a highly unregulated medical course to patients' treatment.

Concerns have been raised over the quality standards of both packaged branded generics and packaged true generics. The Indian regulatory apparatus needs strengthening and investment to deal with these complaints and prevent new incidents of contamination and counterfeiting. However, in the absence of this investment, both types of packaged medications stand as viable

options for patients. Prescribed true generics, as opposed to branded generics, could be a cost saving alternative for financially-constrained patients. However, regulation needs to be put into place to encourage the use of true generics and combat the already entrenched prescribing practices which favor branded generics.

The Indian government has made steps towards this goal through the launch of the Jan Aushadhi Kendra program which establishes government run chemists selling vetted true generics at lower prices.^{83,84} The program has, so far, only been implemented in or adjoining public institutions, however it serves as a pilot of what this sort of intervention could look like in the private sector. Yet, implementation of the Jan Aushadhi Kendra program equates to the entrance of a new type of medication, a government-branded generic, into the system. While government intervention ensures that these medications are comparably priced to true generics, and thus less expensive than branded generics, the introduction of a new type of medication into a broken system fails to address the existing issues in both the informal and formal pharmaceutical networks in these areas.

The regular use of informal channels of medication dispensing clearly demonstrates that there is demand and need in this market for lower priced, widely available medication. However achieving this through the introduction of a new set of stores and branding, as in the Jan Aushadhi Kendra initiative, versus through a crackdown on the current practices driving the market towards branded generics seems misguided at best. My model of a peri-urban Indian pharmaceutical market driven by provider decision-making lays bare the need for new and

⁸³ Planning Commission of India. (2011, October). *High level expert group report on universal health coverage for India*. New Delhi.

⁸⁴ Kotwani, A. (2010). Will generic drug stores improve access to essential medicines for the poor in India? *Journal of Public Health Policy*, 31, 178-184.

effectively enforced regulation on both marketing and medication quality to reshape the informal and formal aspects of the bifurcated market. Only an intervention that takes into account both these medication supply channels will make high quality and affordable medication accessible to the low-income populations in these areas who currently depend on both weakly regulated loose medications and undesirably high priced branded generics.

Appendices

I. History of the Indian Pharmaceutical Market

Historically, India has had a complicated relationship with international intellectual property rights. In 1970 the Patents Act set a precedent for the loose regulation of international intellectual property in post-independence India. The act protects process patents, but does not offer the same safeguards for composition or product patents. In India, this allowed for rampant reverse engineering of molecules on the market to make copycat medications through slightly different chemical processes.⁸⁵ From the 1970's through the early 90's these medications were perfectly legal to produce in India, despite violating international regulations on intellectual property. This legal landscape is not unique to India, and led to similar reverse engineering in other pharmaceutical markets, most notably in Latin and South America.⁸⁶ A concurrent lack of funding and infrastructure during these years meant that research and development of new molecules did not take hold in Indian pharmaceutical manufacturing as it had in western Europe and the United States. Companies were also reluctant to bring innovator molecules to the Indian market due to the weakness of intellectual property laws there, and the high likelihood of competition from a lower priced generic copycat molecule. In 1995 the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement put in place by the World Trade Organization (WTO) gave India ten years until 2005 to reform patent protection for the pharmaceutical

⁸⁵ Haley, George T., and Usha C.V. Haley. (2012). The Effects of Patent-law Changes on Innovation: The Case of India's Pharmaceutical Industry. *Technological Forecasting and Social Change* 79(4). 607-19. Web.

⁸⁶ Shadlen, Kenneth C. (2009) The politics of patents and drugs in Brazil and Mexico: the industrial bases of health policies. *Comparative politics*, 42 (1). pp. 41-58.

industry.^{87,88} Under TRIPS product patents for pharmaceutical products were enforced beginning on January 1st 2005, and patents filed in the interim decade were required to be kept and processed beginning in 2005 as well. This, in conjunction with a growing, although still small in comparison to the general population, Indian upper class has led to the introduction of more true innovator molecules into the Indian pharmaceutical market.

Another important aspect of the Indian pharmaceutical market is the internal capacity to make and manufacture medications. The beginnings of Indian pharmaceutical manufacturing date from the colonial era. Prior to World War II only about 13% of market demand was met by domestically produced medications.⁸⁹ However, the war cut off much of the foreign supply to the country and Indian companies were established to fill this gap in the market raising domestic production of medicines to meet about 70% of countrywide demand. Post-independence loose licensing laws also made India an appealing place for multi-national corporations (MNCs) to set up manufacturing plants. However, for the most part these MNCs did not invest in facilities for the production of the raw ingredients of drugs and instead set up “formulation” or packaging plants to turn imported raw active ingredients into capsules, ointments, and other finished products. In 1956 the Indian government changed its industrial licensing policy to require MNCs who engaged in formulation manufacturing in the country to also invest in facilities to manufacture their bulk product. In addition, the Indian government also moved to encourage the

⁸⁷ TRIPS and pharmaceutical patents: developing countries’ transition periods [Fact sheet]. (2006, September). Retrieved 2016, from World Trade Organization website: https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm#pharmsandags

⁸⁸ Raju, K. D. (2006). TO-TRIPS obligations and patent amendments in India: a critical stocktaking. *Journal of Intellectual Property Rights*, 9, 226-241.

⁸⁹ Mazumdar, M. (2012). An overview of the Indian pharmaceutical sector. In *Contributions to Economics: Performance of pharmaceutical companies in India: a critical analysis of industrial structure, firm specific resources, and emerging strategies* (pp. 17-44). Heidelberg, Germany: Physica-Verlag.

growth of domestic companies who were manufacturing molecules all the way from the chemical components to the final formulation. The policies worked and domestic pharmaceutical companies experienced a surge in market share in the late 1970's and 1980's. By the end of the 1980's MNCs had lost about 20% of the pharmaceutical market in India to domestic growth.

Even as the pharmaceutical market grew in India and transitioned to Indian companies, investment in research and development remained low. In the fiscal year of 1981-1982 only 1.5% of total pharmaceutical sales was reinvested into R&D. Even by 2005 the average R&D investment by Indian companies was equal to 4% of their sales compared to the 10-15% averaged by global firms. This is partially because the majority of R&D in India focuses on process improvement, a less costly side of R&D than product development. Another subset of R&D focuses on minor improvements to existing products, such as longer-lasting formulations or delayed release capsules.

II. Interview Guides

A. Household

Part 1

Observations:

- Observe house/ what items do we see there (to get at socioeconomic status)
 - TV transportation
 - how many rooms
 - bathroom inside or outside?
 - roof?
 - caste?
 - religion?
 - If possible take a photo as a visual reminder

Demographic Info

- Were you born in this area? How long have you lived here/in this area? Do you have family nearby?
- (exit interview) Where do you live? Do you work outside the home? (If so) Where do you work? (On map)
- How many members are in your family? How many kids do you have and how old are they? Who lives with you?
- Did you have the chance to go to school? Up to what level were you able to study?
 - What about our family members? What is the highest education level in your family?
- What do you/members of your family do for a living?
 - How much do you/member of your family earn from these jobs in a month? (can use smaller time frame until one works, ie week, day etc.)
 - How often do you/member of your family get paid? Are you/they paid regularly?
- What are things that you spend money on every month? (Possibility for prop cards showing common expenditures)

Social Network

- Do you have free time (time you spend not working in the house or outside of it)?
 - (If so) what do you do and how often? Who do you spend this time with? Anyone outside of your family?
- Do you get together with people in the community? What do these gatherings look like? (cultural events, chai at people's houses, meeting place)
 - Do you go to a place of worship?
- Who are your friends/social or business relations within the community?
- If we wanted to spread information about a new x to everyone in your village to whom do you suggest we speak?

Motivations

- What are you hoping for your children? Is there anything that you are concerned about for the children's future?
 - What are the barriers to these goals?

Part 2

Healthcare Experiences

Previous Health Experiences

- What does health mean to you? How would you define the word "healthy"?
- You spoke to us before about your/your family's goal of XXX. Are health emergencies or poor health a barrier to these goals?
 - How often is someone in the family sick?

Choice of Provider

- Where do you go when you are sick? Why? When was the last time?
 - How often do you go to a provider/pharmacy? (How many times in the last 6 months?)*
- **Do you have a regular provider that you go see?**
 - **How did you first find this provider? Why did you select them?**
 - **Have you ever gone to a different provider? Why?**
- How do you attempt to improve the health of your family/ protect against health emergencies?
- If your provider moved away, how would you choose a new one?
- **What are three major factors you consider in selecting a provider?**
 - **(don't prompt unless necessary) Cost? Location? Training?**

Physician/Patient Interaction

- What is your last care provider interaction like?*
- How long is it? who talks?
- Do you feel respected?
- What could they do better?
- Who was the provider?
- Was this typical?
- (if household) Thinking back to the last time that you went to see a doctor, was the visit successful?
 - (if exit interview) Do you feel that your visit to the physician today was successful?*
 - Why do you feel it was successful/unsuccessful? *
 - What did you see them for?
 - ! What information did the physician give you?
 - ! If not specific, "Did the physician tell you what caused _____ (xx symptoms)?"
 - Did the provider give you any medications? Do you remember what they were? (household:
 - Did they work? exit: Do you think it will help you?)*
 - Who did you go to see for this visit? (household) Had you seen them before?

- How long ago was this visit? (household)*
- **Do you remember any of the reasons that you have visited a physician in the past two month?**

**What about members of
your family?**

- Do you remember what the doctor/chemist told you about the illness?*
- *(After Week 1- fill in with three common illnesses if they did not already name them)*
Have you ever seen a physician or chemist for ____?*
- Did he prescribe you a medication? Do you recall what it was?*
- If someone different in your family was sick, would you go to the same place/provider?*
- What other places could you go for care?
- In the past year, where have you gone when you are sick? Is there anywhere else you have ever gone?
 - Are any of these places outside your community/neighborhood?
 - (If yes) Where? What was the experience like?
 - Have you ever been to the (insert local health centers and hospitals here)?
 - How was your experience?
 - Why did you choose to go to the hospital?
- Has a doctor ever been unable to treat you? Why? What did you do?*
- Have you ever had to see more than one doctor for a condition? *
 - What was your reason for seeing a second doctor?
 - How did you find the second doctor?
 - In what way was the second provider different from the first?
- If you thought you needed a surgery or if you have ever gotten a surgery, where would/ did you go?

Comparing healthcare

- Do you feel that you have good access to health care?*
- Do you have any concerns about the health care you receive?
- Do you think that people in other parts of the city receive better care?
 - If so, what do you think makes their care better?
 - Do you think that the providers are different in big cities versus in more rural areas? What makes them different?
- Have you ever been frustrated by the care you received? Why?
 - Have you stopped using medications because they didn't work? Have you used a medication for less time than what the doctor told you? If so, why?
 - (if so) What did you do with the extra medication?
- Are there any financial barriers to receiving good care?

Patient-Chemist Interaction

- *If possible have interviewees show us the medications they currently have/are taking, or where they keep these medications. Write down all medications.*
- **Where do you go when you need medication? Do you need to go to different people based on the medications you need?**
 - Is there a reason you normally go to this place? Location, familiarity etc?

- In the past 6 months, have many times have you been to a chemist?
- Have you ever gone directly to a chemist without visiting a physician first?
 - What was the reason for the visit?
 - Did you know what medication you wanted before you visited the chemist?
 - How did you learn about the medication that you needed?*
 - How often do you get your medications from the chemist vs the physician?
 - Do chemists ever recommend treatment to you? If so do you follow the chemist's advice?
 - Has a chemist ever told you something different than a doctor and if so what did you do?
 - Do chemists give you consultations? Do you ever go to a chemist to talk about your symptoms?
 - Do you need to take anything with you to go to the pharmacy?
 - written prescription needed?
- Do you find that different chemists/stockists have different medications available?

Part 3

Patient Knowledge of Medications

- Do you know the names of the medications you or people in your family most often take?
 - Why does your family take these medications?*
 - Do you know the side effects of the medications your family takes?
- Where/ from whom do you learn about medications?
 - Have you heard about certain medications from ads? From ASHAs?
 - Have you ever spoken with a different member of the community about medications?
 - Are there illnesses that you believe need to be cured by drugs? Are there illnesses that can be cured without medication?
- If your child had [insert illness] would you know what medication they should take?
 - ex. fever, diarrhea
- Whose opinions about drugs do you value/trust?*
- What information do providers give you about the medication? Does this vary among providers?
 - Does he tell you how long to take it and what doses?
 - Does he tell you about possible side effects?
 - Do you trust your provider's information on medications he prescribes?*
- Do you bring up medications first at medical visits or do providers bring them up first?
 - Do you feel like providers ever prescribe you more medication than is necessary?
 - Is there such a thing as good drugs and bad drugs? If so, how do you know which is which?

Efficacy of Prescribed Medication

- When you have taken medications in the past, have they been effective at treating your illness?

- Have you ever been given a medication that did not help your sickness? What did you do?
 - Prompt: would/have you changed providers if you thought the medication did not help you feel better?
- Have you heard of/ do you know pharma reps in your community?

Monetary Tradeoff

- When are you willing to pay more for a medication?
 - generic vs branded generic vs brand name?
- About how much do you spend on medications when you do buy them?
- Do different pharmacies or providers charge different prices for the medications?
 - (if yes) Does this influence which pharmacy you choose to purchase from?
- Do you ever not have the money to pay for a medication that you need?
- If a doctor tells you to buy a certain amount of drugs do you buy all of them?
- What did the doctor tell you to buy the last time you were ill? How much did you buy, and how did you take it? *
 - Do you ever buy more medications than the doctor recommended? *
 - (If so) How do you decide to buy this extra medication? *
- Do you think doctors/chemists are ever paid to prescribe certain drugs? *

B. Provider

Part 1

Observations

- What sort of materials/equipment do you see in the clinic?
- Is it clean?
- Are there employees?
- How many rooms are there?

Demographic

- Where did you grow up?
- Who did your family see for care when you were a child?
- Where do you live? Where do you work? (On map)
- How many members are in your family? How many children do you have and how old are they?
 - What do the members of your family do for a living? Are they in the medical field?
 - What is the highest education level in your family?
 - How far did you get in your schooling?
- Did you have any other jobs before you became a provider?
- **How did you first enter the medical field?**
 - When you first started working, how did you learn about being a medical provider?
 - Did you ever consider going to medical school or pursuing more training? If so what were the barriers to going?*

Mapping

- How did you first decide to work here?
- How do you feel about your role in the community?
 - Do you feel respected within your community?
 - If not, why? What do you think could make you better respected?
 - Do you know if you have any kind of reputation in the community?
- What area do you believe your patients are from? (Use laminated map and draw with expo marker)
 - Do you personally know any of your patients?
 - Do you ever visit patients at their homes?
 - Do you see most of your patients more than once? On average, how often will each patient come in per year?

Part 2

General

- What are your normal hours?
- How many patients did you see yesterday?*
- Is this typical for you?
- If not, what is the typical number of patients you see per day?

- I know that working in the medical field can be tough and is not always consistent, how would you describe a successful day for you?
 - What makes it successful?
- What do you think is the most important thing to patients?

Common Conditions

- **I am trying to learn about the types of medical conditions that are prevalent in the community.**

In the past week, what have been the top 5 most common conditions that patients have presented with?

- Of the ____ patients you see per day, how many present with one of these illnesses?
- (If different than top 3 illnesses mentioned by other physicians) **Do you ever see patients with ____?**

When was the last time you saw a patient with this condition? For each condition:

- Do you have a specific name for that condition? (if not provided)
- Why do you think this is a common condition in the local community? What seems to cause the condition?*
- **For _____, what do you recommend to your patients?**
- **Are there any medications that seem to work well?**

Follow-up

- Are you able to follow-up with any of your patients to see if the treatment has worked?
- Has a patient ever returned because a medication or treatment did not work?
 - What did you do?
 - Have you ever had to turn away a patient because you were unable to treat them?

Turning away patients

- Are you selective in any way about which patients you treat?*
 - Do you treat any patients from outside the local community?
 - **Are there any conditions that you are not presently able to treat?**
 - What kind of constraints do you have?
 - Do your patients ever need surgery or another procedure that you are unable to provide?
 - Are there any other reasons that you do not treat a patient
 - Do you feel that you enough resources to treat patients all the patients who come to you? (financial constraints, more training, access to equipment, education)*
 - Is education a constraint for you?
 - If it was offered would you be interested in a supplemental training program?*
- Additional after first week:**
- *(Fill in with conditions others will not treat)* If you saw a patient with _____, do you have the resources to treat them?

System of Referrals

- Do you feel pressured by the community to provide treatment to everyone?

- Do you know the other local providers in the area? What kind of relationships do you have with other local providers?*
- Public sector hospitals?
- Private physicians?
- Have you ever sent a patient to another provider?*
- How do you choose who to send your patient to?
- When was the last time you sent your patient to another provider?
- Do you ever refer patients to see a specialist? Where do you find the specialists?
- Do you think some of your patients need to see a specialist or surgeon but are unable to?
 - If so, why?
- Has a patient ever come to you after seeing another physician? Were they sent to you? Who referred them (private sector formal, private sector informal, public sector?)

Business Finances

- What are your main expenditures for your practice? (Possibility for prop cards showing common expenditures)
 - Do you often feel financially stressed?
- Do you know if there are any cheaper alternatives to the same medications?
- What are your main sources of revenue?
- Do you have employees?
- What other providers are in your area?
- Are you ever worried that your patients will leave you for another provider?
- Why do your patients choose you over other providers?*

Part 3

Are you able to provide patients with the medications they need directly?

If yes → Providers as dispensers

If no → Providers who do not dispense

Providers as Dispensers

- *Possibility for “Walk in Their Shoes”*
- **Why did you choose to keep medications at your clinic?**
- Which medications do you keep in the clinic?*
- How did you choose which medications to keep in the clinic? *
 - How did you first learn about the medications?
- Of the ___ patients you see in a day, how many receive medication at the end of the visit
- **Which medication do you provide most frequently? Why?**
- Is the cost of the visit paid separately from the cost of the medication?
- Do you know how much the local chemists or physicians charge for the same medications?

- Is it difficult to charge competitive prices and still make enough money for yourself?
- Is there a convenient way for you to get the medications that you need?*
- How did you find this source? What company do they represent?*
 - Can you describe your last encounter with ____?
 - Was this typical?
 - Did you have the opportunity to choose between different suppliers?
 - Do you have a good relationship and trust this source to give you the correct medications?
- **Do you wish you could learn more about the medications you have? What are you hoping to learn?**
 - Does ____ (medication provider from above) give you information about the medications they provide? Do you trust this information?
 - Do you ever feel pressured by them to prescribe certain medications?
- If there was a way you could learn more about the different medications that are available, would this be helpful for you?*
- What are you hoping to learn?
 - What do you think is the best way to spread information to other providers?
- Are you able to make money from distributing medications?
 - How much do you pay for the antibiotics (/something that all providers are likely to carry)?
 - How much do your patients pay to receive (common Rx)?
 - If a patient cannot pay for the medication, what do you do?
 - Do you think patients would go to a chemist or different provider if you charged more?
- When you give a patient a medication, what do you tell them about the medication?*
- How do you determine how much medication to give them?
- Do patients ever ask you for a specific medication?*
- How do you think your patients learn about the medication?*
- Have you ever recommended that a patient obtain a medication that you do not have?*
- Do you send them to a particular chemist? Why?*
 - Which medications do you prescribe but do not carry?

Providers Who Don't Dispense

- Is there a particular pharmacy or dispensary that you recommend to your patients to fill your prescriptions?*
- Why this pharmacy? Do you know the owners?
 - How do you tell them which medication to get and how much?
- What information do you provide your patients about their medications?*
- Which medications do you give to patients most frequently?
 - How did you first learn about these medications?
 - Do you feel confident in the medications you prescribe?
- If there was a way you could learn more about different medications that are available, would this be helpful for you?*
- Who would you trust to learn from?

- What do you think is the best way to spread information to other providers?

C. Chemist/Pharmacy Owner

Part 1

Demographic

- Where are you from?
 - (If not local)
 - How long have you been here?
 - Why did you decide to move to this area?
- Who do you live with?
- What are the occupations of people within your family?
 - Do any of your friends or family members have medical training?*
 - Formal? Informal? Probe deeper
- How long have you been working as a chemist/pharmacist?
- **What sort of occupational experience/education have you had prior to holding this post?**
 - Would you have been interested in more training before taking this post?

Motivations

- What are your goals and responsibilities as a chemist?
 - How do you plan to achieve these goals/ fulfill these responsibilities?
 - Is it your responsibility to make sure customers use their drugs correctly?*

Business Format

- Is this the only job you work? What hours do you work during a week?
- Do you have regular customers?
 - How often do they come in? Do you see or spend time with them outside of the shop?
 - Do you live nearby them?
 - Can you show me on this map where you think your customers come from?
- What are the costs/sources of revenue for your business?
 - Are you willing to pay more to stock brand name medications as compared to generic? Why?
 - What price do you pay for medications?
 - What price do you sell them for?
 - How would you expand your business/make it more profitable?
- What are the top five drugs you dispense?

Part 2

Interactions with other chemists

- How many chemists are there in this area?*
- Are you worried that your customers will use these other chemists instead of you?
- Do providers in your area directly dispense drugs? Are these public sector or private sector providers? Formal or informal? Do you view them as competition?

- Do you ever speak with other chemists? Do you feel other chemists have knowledge of medications that you do not? Do you feel you have greater knowledge of medications than the average chemist?*
- If so where do you think they/you got this information in comparison to others?
- Are there services other chemists do not provide that you do provide? What and why?
- Are there services other chemists provide that you do not provide? What and why?
- Why do your customers choose your shop over other shops?
 - What do you think are 2-3 things customers value in a pharmacy?
 - What do you think customers expect from you in a typical interaction?
 - Would providing poor quality drugs hurt your reputation in the community?
 - What do you think customers expect out of a medication? How long does it take a customer to decide a medicine is not working?
- Would knowing more about the medications you provide help your business?*
- Do you ever turn down customers' requests? Why? Can you give a specific example of a time you had to turn down a customer's request?

Part 3

Chemists as Care Providers

- Do you ever consult for customers? Do people ever come in with a set of symptoms and ask your advice on what to take? Do you feel qualified to diagnose illnesses?*
- Do people ever ask you for more general advice on prescriptions?*
- Do you ever talk to patients about how to take the medication?*
- Do you ever recommend medications to customers different from those on their prescriptions/what customers ask for?
 - Why?
- If a patient cannot afford medication what do you usually recommend?
- If customers have extra medication left over what do you think they do with it? Do they ever try to return it to your pharmacy?
- If a customer comes in with a prescription for multiple medications do they ever ask you to make recommendations about which medication they need?
 - (If yes) How do you decide which medicine to recommend?*
- What do patients generally want to know about the medications?
 - Cost? what to use it for? dosage? mechanism? branding? (wait to prompt with specific ideas)

Prescriptions and Lack Thereof

- How many of your customers yesterday came in with a written prescription? What were the dates on the prescriptions (when was it from, a month ago? a year?), how many were current prescriptions?
 - How do patients typically ask for medications? (physical description?) (Written prescription?) Do people ask you directly for drugs by name?*
 - Are there any medications that you cannot sell without a prescription?
- Which medications do you sell in loose form?
 - Which medications, if any, do you sell by the pill? By the strip?

- If a patient asks for a specific medication or an antibiotic without a prescription, would you ask them why they were trying to purchase this medication?
 - (If no) why not?
 - (If yes) Can you give me an example of a time this has happened to you?

Information

- Would your customers be interested in information guides on the drugs in your store?
- **Would you be interested in receiving more information about the drugs that you sell?**
 - For instance if there was a pamphlet with pictures on it that came with the medication as it was dispensed do you think people would be interested in looking at this? (If we are seeing lots of chemists, a prop could be useful)

Networks

- **Do you ever talk to providers? Are there certain providers that send patients your way?**
 - What type of providers are these (private/public, informal/formal?)
 - How often do you interact with providers?
 - Do you give any compensation to providers that refer to your dispensary?
 - How did you make these arrangements?
 - Why did they choose you over other chemists?
 - Do providers tell you any information about the drugs?*
 - Do you think that care providers ever get compensation from pharma reps for prescribing certain medications?*
- How do you know which medications you should stock?
 - Do providers ever talk to you about what medicines you should have in stock?
- How many of your patients in the past week do you think came directly from a care provider encounter versus straight to you without first going to a doctor?*
- Is this typical?
- Do you employ third party “chemist reps” who bring you customers?
 - How did you make these arrangements?
 - Is this a common practice among pharmacies in this area?

Pharma Rep Interactions

- Where do you get the medications you stock?
- How often do you interact with wholesalers?
 - Describe your last interaction with a wholesaler/provider? Was this typical?
- How often do pharmaceutical reps come by your store?*
- From which companies? Which medications do they give you information about?
- What was your last interaction with a medrep like?
 - Is this typical?
- Do you trust the information pharma reps give you about medications?
- Do you often stock the same drugs that the pharma representatives provide?

Pharmacy Owner Discussion Guide

Demographics

- Where are you from?
 - (If not local)
 - How long have you been here?
 - Why did you decide to move to this area?
- Who do you live with?
- What are the occupations of people within your family?
 - Do any of your friends or family members have medical training?*
 - Formal? Informal? Probe deeper
- How long have you managed/owned this pharmacy? Do you manage/own more than one?
- What sort of occupational experience/education have you had prior to holding this post?
 - Did you work as an attending pharmacist before opening your own pharmacy?
 - Is there someone above you who signs off on official documents and prescriptions? (idea of a signature pharmacist)
 - Would you have been interested in more training before taking this post?

Motivations

- What are your goals and responsibilities as a pharmacy owner?
 - How do you plan to achieve these goals/ fulfill these responsibilities?
 - Is it your responsibility to make sure your customers use their drugs correctly?*

Business Format

- Do you have any employees? How many?
 - (If so) What training do they go through? What compensation do they get?
- How often do you go into your store(s) to meet with your employees per month (year, week)?
- Do you ever interact with customers?
 - Can you show me on this map where you think your customers come from?
- What are the costs/sources of revenue for your business?
 - Are you willing to pay more to stock brand name medications as compared to generic? Why?
 - What price do you pay for medications?
 - What price do you sell them for?
 - How would you expand your business/make it more profitable?
- What are the top five drugs your pharmacies sell?
- Are you a member of the The Retail and Dispensing Chemist Association (RDCA)?
 - What do you view as the role of this organization in regulating pharmacies?

Part 2

Interactions with other pharmacies

- How many pharmacies are there in this area?*
- Do you ever worry about losing business to other pharmacies in the area?

- Do providers in your area directly dispense drugs? Do you view them as competition?
- Are there services other pharmacies do not provide that you do provide? What and why?
- Are there services other pharmacies provide that you do not provide? What and why?
- Why do your customers choose your shop over other shops?
 - What do you think are 2-3 things customers value in a pharmacy?
 - Would providing poor quality drugs hurt your reputation in the community?
 - What do you think customers expect out of a medication? How long does it take a customer to decide a medicine is not working?
- Would knowing more about the medications you provide help your business?*

Part 3

Chemists as Care Providers

- What do patients generally want to know about the medications?
 - Cost? what to use it for? dosage? mechanism? branding? (wait to prompt with specific ideas)

Prescriptions and Lack Thereof

- Are there any medications that you cannot sell without a prescription?
- Which medications do your pharmacies sell in loose form?
 - Ie Which medications, if any, do they sell by the pill? By the strip?

Information

- Would your customers be interested in information guides on the drugs in your store?
- Would you be interested in receiving more information about the drugs that you sell?
 - For instance if there was a pamphlet with pictures on it that came with the medication as it was dispensed do you think people would be interested in looking at this? (If we are seeing lots of chemists, a prop could be useful)

Networks

- Do you ever talk to providers? Are there certain providers that send patients your way?
 - How often do you interact with providers?
 - Do you give any compensation to providers that refer to your dispensary?
 - How did you make these arrangements?
 - Why did they choose you over other pharmacies?
 - Do providers tell you any information about the drugs?*
 - Do you think that care providers ever get compensation from pharma reps for prescribing certain medications?*
- How do you know which medications you should stock?
 - Do providers ever talk to you about what medicines you should have in stock?
- Do you employ third party “chemist reps” who bring you customers?
 - How did you make these arrangements?

Pharma Rep Interactions

- Where do you get the medications you stock?
- How often do you interact with wholesalers?
 - Describe your last interaction with a wholesaler/provider? Was this typical?
 - Are there other wholesalers/medreps you could work with?
- How often do pharmaceutical reps come by your store(s)/office?
 - From which companies? Which medications do they give you information about?
 - What is a typical interaction with the like with a medrep?
 - Do you trust the information pharma reps give you about medications?*
 - Do you often stock the same drugs that the pharma representatives provide?

D. Medical Representative

Part 1

Demographics

- Where are you from?
 - Where do you live now?
 - Show me on this map
- Who do you live with?
 - What are your family members' occupations? Are any of them employed in the medical field?
- What was your highest education level?
 - Have you worked for another pharma company before?
- How long have you been working as a medrep?
- Have you worked in other areas of India? How long have you been based in Mumbai?
 - How long do you plan to work in this area?

Part 2

Motivations

- Why did you want to be a medrep?
- What motivates you to work?
- Do feel that your work is valuable and worthwhile?
- Does your job performance affect your reputation within your community or your company?
- What are your career goals?
- Are there opportunities for promotion?
 - How long do you want to be a medrep for?
- Why do you work in this location?
- What do you view as your central responsibilities?*
- What earns you praise from your superiors? criticism?
- How will you achieve your career goals/please your bosses/fulfill your responsibilities?
- What would you consider a successful work day?
 - How does your company measure your success?
 - Are there certain goals you must meet?
- Could you improve your job performance? if so how?
- Is knowing information about medications important to accomplishing your goals?*

Part 3

Knowledge about drugs

- **Where do you get your information about these drugs?**
- What information does your company provide you with about the medications you sell?*
- Whose medical opinions do you value?*
- Inside company?
- Outside of company?

Job Description

- Did you have another occupation before becoming a pharmaceutical rep? If yes, what was it? What made you decide to become a pharmaceutical rep?
- How did you become a medrep? What was the recruiting process like?
- **How were you trained by the company you are working for?**
- How do you get compensated?
 - How are you compensated for your work? Is it a daily wage, by the number of medicines sold to pharmacies (commission)?
- Does your company make the medications that you sell?
 - If not, where do they get them from?
- Are you aware of the difference between the cost of making this medication and the amount you sell the medication for? (figuring out what is the price markup)
 - Does this differ for different medications?
 - Are you compensated more if this difference is larger?
- **Describe what you did yesterday: where did you go/ who did you talk to?**
 - About how many of pharmacies/providers do you visit in a day?
 - What was your working day yesterday like?
- Do you interact with chemists?
 - If yes, describe your last interaction with one.
- Do you interact with wholesalers?
 - If yes, describe your last interaction with one.
- Do you ever speak directly to care providers?
 - Where do these care providers work? In government centers? In the private sector? Less formal clinics?
 - Are there certain pharmacies/providers you work with more often than others?
 - Describe your last interaction with an informal? private formal? government?
- Do you ever speak with ASHAs or community health workers?

Providing Drugs

- Are you assigned customers or do you seek them out on your own?
 - (if not assigned) How do you meet the people you provide medications to?
 - How do you choose among customers?
 - Who is a desirable customer? Why?
 - training, experience, patient base, trustworthiness?
- **Who do you provide medication to? Who are your customers?**
 - chemists? wholesalers? formal providers? informal providers? government?
 - Who do the chemists/ wholesalers sell to?
 - What areas do you serve (map)?
 - Are there certain areas of the city you work in more often?
 - Why? Do the drugs that you recommend to providers differ by community? Are there differences in the needs of the community? in what they can afford? what they are willing to buy?

- What areas are you most successful (map)?
- How often do you meet with your customers?
 - Describe your last interaction with a customer? (Can skip if earlier chemist, wholesaler, care provider questions covered a customer-rep interaction)
- Do you ever meet with groups of providers? Or do you consult individually?
 - If they do meet in groups: What do you discuss?
- Do you ever meet with providers about prescribing more of a given medication?
 - Do chemists ever request that you do this?
- **What kind of information do you share with providers about the medications that they buy?**
 - EX. Side effects? Risk of overusing of antibiotics/ steroids? Sterilization of needles?
 - Do they generally choose the medications or do you make recommendations?*
 - **What do providers generally want to know about the medications?**
 - cost? what to use it for? dosage? mechanism? branding? side effects?
 - Do providers care whether a medication is branded or generic?
 - In your opinion, does it matter whether a medication is branded or generic?
 - Does the information you provide influence their decision to purchase a given drug?*
 - **Does the information you provide influence how providers prescribe the medication?**
- Why do chemists/physicians buy the drugs that they buy?
 - Cost? Efficacy?
 - Do they care about side effects? Long-term ones?
 - Do different types of providers want different medications?
- What are the top five medications that you sell?
 - Do you know how much they cost to produce? (for higher ups. to get a sense of the price markup.)
 - How much do you sell each of them for?
 - Do you know how much do providers/chemists charge for these medications?
 - What illnesses to these medications treat? When should they be used?
 - What illnesses do you believe providers/chemists prescribe these medications for?
 - What are the side effects of each of these medications?
 - Are there alternatives to these medications?
 - Why are these medications more popular than the alternatives?
- What do you think are the top five drugs that physicians prescribe? (might be the same)

Pharma Competition/ Marketing Strategies

- Do you know any other companies or individuals who sell medications in these areas?
 - (show map)
 - Can you mark down on the map where they sell medications?
- What other companies sells medications in the same areas as you?
- Why do your customers buy from you instead of these others?
 - Low prices? better drugs? better reputation? they are your friends?

- Are there any marketing schemes for the medications you are working on? (ie buy 12 strips get one free)
- How do you convince customers to buy your drugs?
 - Do you use different techniques on different types of customers?
- Do you ever talk with other pharma representatives? What sort of strategies do other pharma representatives apply?
 - Do you think that some pharmaceutical representatives offer monetary compensation for prescribing or dispensing certain drugs?

Providers' Knowledge

- Do you notice a difference between informal and formal providers? If so, what are they?
- Do different providers prescribe the medications differently?
 - Why?
 - How do chemists, the government, formal private and informal private differ?
- Do some providers prescribe medications for unintended uses?
 - Why?
 - consumer demand, lack of knowledge, greed?
 - Are these uses of the medication harmful to the patients in your opinion?
 - Do chemists, formal, informal, or government providers misuse medication more or in different ways?
- Are there any specific examples of misuse of medication that you have observed?
 - Describe the last example you observed.
 - Are there any patterns of misuse that you have observed?
 - Would you report this misuse to your superiors?
 - if it was harmful to households?
- Would observing misuse make you/your company less likely to sell to a given provider?
- Do other pharma reps within your company care if medication is misused?
 - pharma reps in other companies?
- **Is it your responsibility to make sure medications are prescribed correctly?**
 - Does it help/hurt your reputation in the community or within your company?
 - Is there anything you do to help providers prescribe correctly?
 - Could you do anything else to help them prescribe correctly?
 - Do you think your superiors care if medications are prescribed correctly?
 - Is there anything your company could do to help providers prescribe medications correctly?
 - Give providers more knowledge, sell medications with less side effects?
 - Do you think providers want to learn how to prescribe medications correctly?

Consumer Knowledge

- **Do you ever talk with non medical individuals? (ie households?)**
 - If yes, describe your last interaction with one.
 - Was this typical?
- Does your company make any efforts to inform drug consumers about your drugs?
 - Do other sellers of medication?

- Would drug consumers use your drugs more if they had more information about your drug?*
- Would informing drug consumers help counteract medication misuse?
- Would distributing information guides about your drugs to households help your company?

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