

The Private Sector Market for Diarrhea Treatment in India

April 2012

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Abbreviations

AIOCD	All India Organization of Chemists and Druggists
AIIMS	All Indian Institute of Medical Sciences
AYUSH	Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy
BMGF	The Bill and Melinda Gates Foundation
C&F	Carrying and Forward Agent
CDSA	Clinical Development Service Agency
CHAI	Clinton Health Access Initiative
CME	Continuing Medical Education
CST	Central Sales Tax
DBT	Department of Biotechnology
DCA	Drugs and Cosmetics Act
DCGI	Drug Controller General of India
DCR	Drugs and Cosmetics Rules
DLHS	District Level Household Survey
DPCO	Drug Price Control Order
FDA	Food and Drug Administration
FMRAI	Federation of Medical and Sales Representatives Association of India
GOI	Government of India
IAP	Indian Academy of Pediatrics
IMA	Indian Medical Association
IMC	Indian Medical Council
IMNCI	Integrated Management of Neonatal and Childhood Illnesses
INR	Indian Rupee
IP	Indian Pharmacopoeia
JSI	John Snow International
KOL	Key Opinion Leader
MR	Medical Representative
NGO	Non-governmental organization
NFI	National Formulary of India
NPPA	National Pharmaceutical Pricing Authority
OPPI	Organization of Pharmaceutical Producers of India
ORS	Oral Rehydration Salts
OTC	Over the Counter
PSI	Population Sciences International
RMP	Rural Medical Practitioners
STG	Standard Treatment Guidelines
UNICEF	United Nations Children's Fund
UNSE	United Nations Secretary General Special Envoy for malaria
WHO	World Health Organization

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Executive Summary

Context

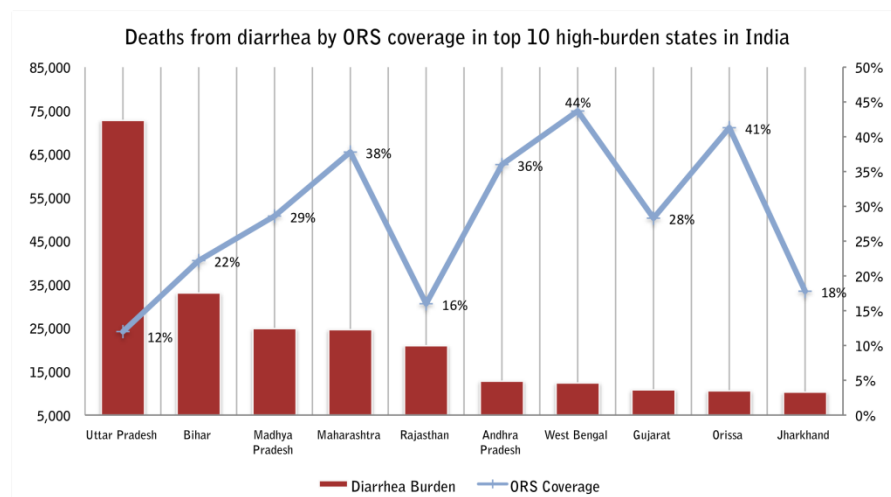


Figure 1: Diarrhea mortality and ORS coverage in India. *Source:* National Family Health Survey India, 2007-2008.

Diarrheal diseases account for approximately 235,000 of the 2 million¹ deaths of children under the age of five in India each year. It is estimated that treatment of diarrhea with Oral Rehydration Salts (ORS) and zinc, as recommended by the WHO, can avert nearly 90% of the deaths. However, the uptake of this treatment remains unacceptably low. Nationwide, only 39%² of caregivers use ORS to treat diarrhea, and the use of zinc

in high-burden states is almost negligible at less than 2%³. Nearly 26% of

caregivers do not seek treatment for diarrhea, and those who do seek treatment are typically treated with antibiotics or anti-diarrheals⁴.

Improving use of zinc and ORS for treatment of childhood diarrhea presents a significant opportunity to accelerate the reduction of child mortality in India in support of the achievement of Millennium Development Goal 4 and to expand the value of the ORS and zinc market. Accordingly, the Government of India is devising a national strategy to dramatically scale-up access to essential medicines for children, which includes ORS and zinc for diarrhea. As part of this strategy, interventions targeting the private health sector will be essential, since nearly 60%⁵ of caregivers in India seek treatment for diarrhea from a private healthcare provider. Designing high-impact interventions will require an understanding of the current dynamics of the diarrhea treatment market in India and the key barriers hindering the uptake of ORS and zinc at each level of the supply chain. This assessment was performed to contribute to this end by examining the diarrhea treatment market in a way that offers strategic direction for the development of India's essential medicines national strategy.

Methodology

Primary and secondary data collection was conducted between September 2011 and January 2012, which included semi-structured interviews with key informants operating at different levels of the supply chain, a field visit to an international NGO's project site in Lucknow, Uttar Pradesh and a desk review of existing qualitative and quantitative research, and population-based data.

¹ UNICEF. "More than 1 Million Child Deaths in India Can Easily Be Prevented Every Year." Web. Accessed on November 22, 2011. Available at:

http://www.unicef.org/india/health_491.htm

² National Family Health Survey, India 2007-2008

³ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

⁴ Ibid

⁵ Ibid

Background

In India, the quality of health delivery in the public sector is compromised by funding and human resource shortages, leading to frequent drug stock-outs, provider absenteeism and an overall substandard level of care. By default, nearly 80% of outpatient visits in urban and rural areas take place in the private sector⁶. Across India, the ratio of public providers to private providers is 1 to 10⁷.

Within the private health system, a heterogeneous group of providers is found. This ranges from qualified providers that practice allopathic medicine or alternative systems of medicine (e.g. ayurveda, yoga) to unqualified providers with no formal medical education. These unqualified providers, called Rural Medical Practitioners (RMPs), account for 65% of all providers in India and are the most common first point of care for diarrhea treatment⁸.

Demand-side Barriers

Majority of caregivers that seek treatment for diarrhea are not prescribed ORS and zinc. 47% of the 9,298 caregivers surveyed in 10 states in India reported receiving an injectable drug, antidiarrheal or antibiotic for the treatment of diarrhea, in comparison to the 47% prescribed ORS and 1.3% prescribed zinc⁹.

This incorrect prescription behavior is largely driven by low awareness of zinc as the recommended treatment for diarrhea and poor perceptions of ORS as an effective diarrhea treatment, leading to an increase in the use of alternative drugs such as antibiotics and anti-diarrheals. Further, a discrepancy exists between what providers and caregivers know about diarrhea treatment, and what they do, referred to as the “know-do” gap.

Studies led in one district in 10 states and specifically in Bihar, Uttar Pradesh and Gujarat have confirmed these findings. For instance, between 9-19% of providers report prescribing zinc as the first-line treatment for diarrhea, however, although 5-21% of caregivers have heard of zinc, only 1-4% of caregivers report being recommended to treat their child with it. This trend extends to ORS, where 90% of provider’s report prescribing the product for diarrhea treatment and between 55-88% of caregiver’s report being aware of it, but only between 15 – 38% of caregivers report actually using ORS to treat their child’s most recent diarrhea episode^{10,11,12}.

These behaviors are driven by the perception that ORS is equivalent to home remedies (e.g. sugar and salt) and both ORS and zinc do not address the “immediate symptoms” of diarrhea – a treatment outcome that is highly valued amongst caregivers. As a result, private providers, who are heavily influenced by caregiver preferences to maintain a loyal consumer base, prescribe alternative medications.

The profitability and affordability of ORS and zinc versus alternative treatments also plays a role in provider prescribing behavior and caregiver preferences. Analysis of retail and provider consultation data found that treatment of diarrhea with ORS and zinc from an RMP is 55% higher than with an antibiotic.

These circumstances have led to a “market trap” for ORS and zinc in India, whereby caregivers and providers do not demand the products due to limited awareness and appreciation of comparative benefits, and suppliers do not promote and distribute the products due to insufficient demand. Consequently, ORS and zinc

⁶ Ramani KV and Mavalankar Dileep. “Health System in India: Opportunities and Challenges for improvement,” Indian Institute of Management, July 2005

⁷ Centre for Policy Research. “Mapping Medical Providers in Rural India: Four Key Trends.” February 2011.

⁸ Ibid

⁹ UNICEF. “Management Practices for Childhood Diarrhea in India.” 2009

¹⁰ UNICEF. “Management Practices for Childhood Diarrhea in India.” 2009

¹¹ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. “Enhancing the Uptake of ORS and Zinc in Targeted Areas of India: Baseline cross sectional survey internal report.” Funded by Children’s Investment Fund Foundation, 2011

¹² Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. “Reducing deaths from Diarrhea in the Indian State of Bihar.” Funded by Children’s Investment Fund Foundation, 2011

are not readily available at the retail level, especially in rural areas; a survey in Uttar Pradesh found only 50% of retailers stocked ORS and 8% stocked zinc¹³.

Supply-side Barriers

Currently, 52 pharmaceutical companies manufacture ORS and 23 manufacture zinc in India, valuing the market for the products at nearly US\$41M annually¹⁴. However, the market is largely controlled by five companies, of which none have achieved the profits or internal buy-in to invest the resources needed to dramatically shift the diarrhea treatment market from antibiotics and anti-diarrheals to ORS and zinc. The scope of the market is also limited by the ambiguous regulatory drug status of zinc, which is not classified and not considered an Over-The-Counter (OTC) product, like ORS¹⁵. As a result, direct to consumer marketing and distribution to non-licensed retailers (e.g. grocery stores) is restricted. In cases where companies manufacture a basket of diarrhea treatments, including ORS, zinc, antidiarrheals and probiotics, competing internal priorities between higher and lower margin products may impact marketing and sales strategies¹⁶.

Recommendations

The market for ORS and zinc has the potential to reach US\$128 million by 2015, an increase of over 200%. Capitalizing on this opportunity by increasing the demand for and uptake of ORS and zinc can significantly accelerate progress on reducing child mortality in India. However, realizing this opportunity will require a joint effort by the Government of India, donors, pharmaceutical companies and non-profit organizations, that balances a willingness to learn from past experiences and test new ideas.

At the top of the supply chain, illustrating the market potential of ORS and zinc in the next three years will be critical to engaging pharmaceutical manufacturers in committing adequate resources to repositioning the products as clinically effective and affordable through innovative marketing tactics and improving accessibility through public-private distribution strategies. The introduction of a co-packaged product in parallel with a multi-channel social marketing campaign may be an attractive option to frame ORS and zinc as the new “gold-standard” treatment for diarrhea. The Government of India, in partnership with non-profit organizations, can play a significant role in communicating this opportunity to the private sector, and guiding them in a way that ensures a double bottom line is achieved.

At the bottom of the supply chain, training RMPs on the recommended diarrhea treatments and influencing key qualified providers on the efficacy of zinc will be critical to increasing uptake. This will require a deep understanding of the factors that motivate these cadres of health professionals to change their behavior and partnerships with influential professional societies. Incentives that impact the livelihoods of providers, reinforced messaging through mobile technology and institutional partnerships structured to build or compromise professional reputations are some ideas that should be explored further. Medical representatives, in partnership with non-profit organizations can play a significant role in communicating accurate messages and collateral in a way that ensures adoption and integrity.

¹³ Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008

¹⁴ ORG/IMS Data, September 2011 MAT

¹⁵ Gitanjali B, Weerasuriya K. The curious case of zinc for diarrhea: Unavailable, unprescribed, and unused. *J Pharmacol Pharmacother* 2011;2:225-9

¹⁶ Interviews with pharmaceutical manufacturers, October 2011

Context

In July 2011, under the leadership of UNICEF and Ray Chambers, the UN Special Envoy for Malaria, a group of partners began developing a new global initiative to dramatically accelerate the scale-up of effective treatment for the three largest killers of children: diarrhea, malaria, and pneumonia. Improving access to malaria treatment and diagnosis has received significant, if still insufficient, attention and funding in recent years. In contrast, scale-up of diarrhea and pneumonia treatment has been largely neglected for the past decade, resulting in less analysis on solutions to achieve large-scale access to these products. The initiative seeks to mobilize additional attention, resources, and concrete action to support 10 countries with the highest burdens of these diseases to design and implement ambitious programs to scale-up appropriate treatment with the goal of achieving universal access by the end of 2015.

As one of these high-burden countries, the Government of India (GOI), with assistance from the Clinton Health Access Initiative and other partners, is developing a treatment scale-up plan to address these three childhood illnesses. Currently, nearly 60% of children in India seek and obtain care for diarrhea, malaria and pneumonia from the private sector¹⁷. This indicates a need for a different approach that includes market-oriented interventions to ensure greater coverage of effective treatments. This is particularly the case for ORS and zinc, the WHO-recommended treatments for diarrhea, since both products are safe for over-the-counter use, indicating suitability for distribution through the private sector. Thus, it is essential to gain a better understanding of the private sector supply chain in order to ensure that these treatments reach the maximum number of children in need.

This report presents the findings of a rapid assessment of the private sector supply chain for diarrhea treatment in India, with the intent of using these findings to inform the GOI broader scale-up strategy.

The aim of this analysis was to:

1. Understand the dynamics that govern the private sector market for diarrhea treatment, including ORS, zinc, and key competing products;
2. Generate a data set to identify the supply and demand barriers to uptake of ORS and zinc;
3. Utilize the data set to directly inform ORS and zinc scale-up efforts in India

¹⁷ WHO India. "Not Enough Here-Too Many There- Health Workforce in India." Web. Accessed on: November 10, 2011. Available at: http://www.whoindia.org/LinkFiles/Human_Resources_Health_Workforce_in_India_-_Apr07.pdf

Methodology

This assessment combines primary and secondary data collection to answer four key research questions:

- What are the current market dynamics of diarrhea treatment in India?
- Who are the key stakeholders in the private sector market for diarrhea treatment in India – what is their role and level of influence?
- What factors are driving the decisions of caregivers, providers and retailers with regards to diarrhea treatment?
- What are the greatest supply and demand barriers inhibiting the uptake of ORS and zinc in India?

This assessment was conducted from September 2011 to January 2012. It included semi-structured interviews with 44 key informants across the supply chain in New Delhi, Mumbai, Lucknow, and Bhopal. This includes: pharmaceutical manufacturers, distributors/wholesalers, providers, retailers, government agencies,

Type of key informant	Number interviewed
Pharmaceutical manufacturer	9
Non-profit organization	9
Stockist	3
Provider (qualified and unqualified)	10
Retailers	10
Government Agency	1
Advertising Agency	1
Consumer Packaged Goods	1
TOTAL	44

Table 1: Key informant interview list

and non-profit organizations (Table 1). Key players in the diarrhea treatment market were identified through competitive research conducted by the Clinton Health Access Initiative in May 2009. Internal contacts in the pharmaceutical industry and non-profit sector in India were leveraged followed by utilization of a snowball methodology to meet additional key informants. A meeting held by the Clinical Development Service Agency in New Delhi, India in August 2011 called “Meeting of Suppliers of zinc Tablets for the Treatment of Childhood Diarrhea” also served as a platform to initiate contact with key stakeholders in the sector. Data collected from these interviews were used to inform the manufacturer and distribution sections of this report.

Desk research was also conducted for this assessment by reviewing studies on diarrhea treatment behavior in India compiled by non-profit organizations UNICEF, AED, and Micronutrient Initiative. Reports that included representative sample sizes in high-burden states were chosen for further analysis and synthesis and informed the caregiver, provider and retailer sections of this report. Google scholar searches were conducted to locate reports outlining the pharmaceutical supply chain, market outlook and drug regulations in India, which were used for the supply chain and regulatory sections of this report.

Lastly, market data on gastrointestinal treatments collected by IMS/ORG for the period of September 2010 – September 2011, was analyzed to determine annual volumes, market size and market share for commonly used diarrhea treatments across pediatric and adult populations. ORS and zinc retail pricing data was shared by a non-profit organization, and cost data was compiled through various sources including key informant interviews, academic papers and grey literature.

Limitations

- Quantitative data is represented in ranges to represent differences across available state-level data. State level findings presented should not be interpreted as national trends
- Data collected from key informant interviews suffer from the common weaknesses of qualitative research. In this case, pharmaceutical manufacturers may have only disclosed publicly available information for legal and competitive reasons

- Primary data collection of a representative sample size was not conducted by CHAI for this assessment, and heavily leverages on existing research and literature. The quality of research was determined by the strength of the partner and/or the sample size of a study

Diarrhea Treatment Private Sector Supply Chain

Overview of the Pharmaceutical Sector

India has one of the fastest growing pharmaceutical industries in the world, valued at \$12.6 billion in 2009¹⁸, of which appropriate diarrhea treatments (ORS & zinc) represent less than 0.03% (~\$41 million)¹⁹. In contrast, antibiotics anti-diarrheals and other gastrointestinal products also commonly used for diarrhea treatment represent nearly 2.06% (~\$259 million) of the market²⁰. Over the last 5 years, the industry has been growing between 13-15% annually, driven primarily by an increase in disposable income and supported by a rise in the prevalence and treatment of chronic diseases, expansion of medical infrastructure, wider coverage of health insurance and the launch of patented products²¹. By 2020, the pharmaceutical market is expected to grow to \$55.0 billion, assuming greater government spending on public health and the provision of insurance coverage for those below the poverty line²². Increased acceptability of allopathic medicine amongst consumers will lead to increased adoption of biologics and preventative medication. Further, a greater propensity to self-medicate has the potential to influence growth in the sale of over-the-counter (OTC) drugs by 14% annually to become a \$14-18 billion market by 2020²³. This is especially the case for therapeutic areas such as respiratory and gastrointestinal, including diarrhea treatments, which have traditionally been treated by providers. Indian ORS and zinc manufacturers can take advantage of this shifting market trend and significantly increase their market share by intelligently positioning their products thereby reducing caregiver preference towards antibiotics and anti-diarrheals. However, experts believe that this growth is heavily predicated on a company's ability to customize products from consumer research, brand products in a way that establishes an emotional connection with consumers, and accept lower margins to increase reach²⁴.

Currently, there are over 20,000 licensed pharmaceutical manufacturers across India. These companies vary in size from small-scale local manufacturers to large production units and include five companies operating under public ownership²⁵. Between 250-300 companies manufacture approximately 70% of the products on the market, with the top 10 firms representing 30% of the whole²⁶. In New Delhi, India alone there are an estimated 95,000 pharmaceutical products on the market²⁷.

Since India had a system of process patents until 2005, the majority of these companies produce generic drugs²⁸. Branded generics (off-patent drugs marketed under a brand name) dominate, accounting for 70-80% of the retail market. However, branded generics are increasingly threatened by non-branded generics that typically offer more lucrative margins²⁹. Both ORS and zinc are sold as branded generic products in India; the profit margins on these products are typically low as product differentiation is not a key sales driver in this category in comparison to price competitiveness. Given the fierce competition in the branded generic market space, the potential for one manufacturer to grab a substantial market share is small; as a result, manufacturers are typically less willing to invest in promotion and distribution expansion activities for a specific branded generic product. Exports also account for a large portion of India's pharmaceutical

¹⁸ Vikas Bhadoria, Ankur Bhajanka, Kaustubh Chakroborty and Palash Mitra. "India Pharma 2020: Propelling access and acceptance, realising true potential." Mckinsey & Company, 2010

¹⁹ ORG/IMS Data, September 2011 MAT

²⁰ Ibid

²¹ Vikas Bhadoria, Ankur Bhajanka, Kaustubh Chakroborty and Palash Mitra. "India Pharma 2020: Propelling access and acceptance, realising true potential." Mckinsey & Company, 2010

²² Ibid

²³ Ibid

²⁴ Price Waterhouse Cooper. "India Pharma Inc: Capitalising on India's Growth Potential." 2011

²⁵ Anita Kotwani, and Libby Levison. "Price Components and Access to Medicines in Delhi, India." Department for International Development (DFID), April 2007.

²⁶ Price Waterhouse Cooper. "India Pharma Inc: Capitalising on India's Growth Potential." 2011

²⁷ Anita Kotwani, and Libby Levison. "Price Components and Access to Medicines in Delhi, India." Department for International Development (DFID), April 2007.

²⁸ Vikas Bhadoria, Ankur Bhajanka, Kaustubh Chakroborty and Palash Mitra. "India Pharma 2020: Propelling access and acceptance, realising true potential." Mckinsey & Company, 2010

²⁹ Ibid

manufacturing business. Nearly 70% of branded generics manufactured are exported to over 50 countries globally, with United States, Russia, Germany, Australia and United Kingdom accounting for the highest number of imports^{30,31}.

Overview of the Pharmaceutical Supply Chain

The pharmaceutical supply chain in India is exceptionally fragmented, with independent private companies operating at every level of the system (Figure 2). At the top of the supply chain are 20,000³² pharmaceutical manufacturers located across India.

The route by which a health product moves along the supply chain is determined by how the health product is marketed. If a manufacturer chooses to market the health product itself, it will be transferred to a **Carrying and Forward (C&F) agent**. C&F agents are privately-owned businesses that hold a license to sell the health product in the name of the manufacturer to wholesalers. Typically, each manufacturer has 1-3 C&F agents in each of India's 28 states, and each C&F agent works with a maximum of 1-3 manufacturers. Compensation is based on the C&F agent's annual total turnover, ranging from 4% for high turnover products to 10% for low turnover products³³.

While C&F agents lead the distribution of the products, manufacturers handle marketing through the deployment of **Medical Representatives (MRs)** across the country to detail providers and retailers on the clinical benefits of the health product and disseminate academic literature, marketing materials, free samples and brand reminders. There are approximately 100,000 MRs registered in India with the Federation of Medical and Sales Representatives Association of India (FMRAI)³⁴. The size of a company's sales force largely determines the extent of a company's geographic reach. For large company's, this field force typically ranges from between 500 – 2,000 MRs, who are in most cases limited to Class I and Class II towns (>100,000)³⁵. In general, an MR will begin generating demand for a product at the direction of its employer, a therapy group within a pharmaceutical manufacturing company. Most ORS and zinc manufacturers instruct their MRs to start promoting ORS and zinc products before and during the monsoon season in India, which runs from March to July³⁶. According to interviews with select pharmaceutical manufacturers, clinicians are generally not interested in learning about ORS as these products have been detailed numerous times over the last few decades.

When a manufacturer chooses not to market a health product itself, the health product is shipped directly to a **Super-stockist**. Super-stockists are also privately owned businesses, but unlike a C&F agent, they have their own license to sell health products and invest their own capital in marketing and promotion activities. Most stockists have sizeable sales teams, varying from 10-50 depending on the size of the enterprise and the area serviced by it. The sales force is responsible for not only fulfilling routine orders but also for enlisting new retailers, promoting new products and expanding the geographical coverage of the enterprise³⁷. In general, lower-priced branded generics are distributed through super-stockists, and compensation ranges from 2-5% of annual product turnover³⁸.

Both C&F agents and super-stockists distribute health products to **Stockists**, across every district within a given state. On average, a C&F agent or super-stockist will work with anywhere from 2,000 – 7,000 stockists

³⁰ Biospectrum. "India contributes 20% of the global generics market supply." July 19, 2010. Available at: <http://www.biospectrumasia.com/content/090710IND13033.asp>

³¹ Pooja Gupta and Pradeep Manjrekar. "Innovation strategies in the bulk drug industry case study: Unilab Chemicals Pvt. Ltd. and M/s Blue Circle.

³² Ministry of Industry Department of Commerce, Government of India. "Strategy for increasing exports for pharmaceutical products: Report of Task Force." December 2008

³³ Eric Langer and Abhijeet Kelkar. "Pharmaceutical Distribution in India." BioPharm International, September 2008.

³⁴ Federation of Medical and Sales Representatives Association of India (FMRAI). Web. Accessed on December 12, 2011. Available at: <http://www.fmrai.org/>

³⁵ Interviews with pharmaceutical manufacturers, October 2011

³⁶ Ibid

³⁷ Interviews with stockists, November 2011

³⁸ Ibid

across the country³⁹. In India, there are reportedly over 60,000 stockists across the country, each managing the inventory of products from 5 to 50 pharmaceutical companies⁴⁰.

Stockists will either distribute products to sub-stockists, or sell directly to **Retailers** through their own sales force, often offering products on a 21 to 45 day credit policy⁴¹. For example, a large stockist in New Delhi reported supplying products to 500-600 retailers in the city⁴². There are approximately 550,000⁴³ healthcare retailers in India that are divided into two categories: organized and unorganized.

Organized pharmacies account for 1-2% of all healthcare retailers in India and are usually structured as franchises that sell OTC drugs and are situated in urban areas⁴⁴. Experts predict that the growth of healthcare retail franchises is on the rise, especially since the structure allows for volume cost benefits that can potentially be passed on to the consumer. Pharmaceutical companies, such as Ranbaxy Pharmaceuticals and national brands such as Reliance HealthCare and Subhiksha, are setting up retail chains across India, with the intent to squeeze out wholesalers and offer consumers perks such as discounts and loyalty programs⁴⁵.

Unorganized pharmacies, on the other hand, still account for the bulk of healthcare retailers in the country, and extend to providers, grocery stores and *paan* stalls that sell health products. Though the Food and Drug Administration of India orders that only qualified pharmacists can obtain licenses to operate a pharmacy, pharmacists are often hired part-time or only for the use of a signature by pharmacy business owners to fulfill the regulatory requirements⁴⁶.

By law, retail pharmacies must meet the minimum area requirement of 10 square meters to operate⁴⁷. Though small when compared to Western standards, this amount of space is the norm for most unorganized pharmacies in rural India, resulting in a shortage of storage room for products, inability to maintain appropriate temperature conditions for specific products and limited interaction between pharmacy personnel and patient's. Consequently, most unorganized pharmacies only stock health products for common illnesses, and are usually located on busy roads⁴⁸.

A study conducted by the Department for International Health (DFID), UK found that an average pharmacy in New Delhi, India stocks between 10,000 and 15,000 drugs, with 5-50 versions of each medicine from 30-40 stockists⁴⁹. This high number of products, combined with small amounts of space, means that pharmacies stock limited quantities of each product, often requiring a stockist to deliver product daily⁵⁰. It is important to note that these characteristics are unique to a metro, in comparison to a town or village in India.

Some NGOs and private providers (mostly unqualified) also sell and distribute drugs in the country. While NGOs typically partner with manufacturers directly and sell drugs at a subsidized price to caregivers or to the government, private providers typically buy drugs through a pharmaceutical MR or through a retailer. Private providers that are serviced by MRs are privy to the same profit margin as retailers, in comparison to providers who buy drugs from a retailer at a bulk rate.

³⁹ Eric Langer and Abhijeet Kelkar. "Pharmaceutical Distribution in India." BioPharm International, September 2008.

⁴⁰ Ibid

⁴¹ Interviews with stockists, November 2011

⁴² Anita Kotwani, and Libby Levison. "Price Components and Access to Medicines in Delhi, India." Department for International Development (DFID), April 2007.

⁴³ Eric Langer and Abhijeet Kelkar. "Pharmaceutical Distribution in India." BioPharm International, September 2008.

⁴⁴ Ibid

⁴⁵ Price WaterHouse Cooper. "Global Pharma Looks to India: Prospects for Growth."

⁴⁶ Roger Jeffery et al. "Pharmaceuticals distribution system in India." Centre for International Public Health Policy, July 2007

⁴⁷ Anita Kotwani, and Libby Levison. "Price Components and Access to Medicines in Delhi, India." Department for International Development (DFID), April 2007.

⁴⁸ Ibid

⁴⁹ Anita Kotwani, and Libby Levison. "Price Components and Access to Medicines in Delhi, India." Department for International Development (DFID), April 2007.

⁵⁰ Ibid

The model of drug distribution in India outlined above is expected to evolve over the next decade toward more consolidation⁵¹. Influential hospital chains and pharmaceutical companies are increasingly investing in infrastructure, such as manufacturing units, hospitals and retail pharmacy chains, to cut out intermediate wholesalers⁵². Further, over 30 multinational companies in India are opening retail pharmacy chains, threatening the sustainability of independent retail pharmacies that may be unable to compete on price and trade terms⁵³.

⁵¹ Price WaterHouse Cooper. "Global Pharma Looks to India: Prospects for Growth."

⁵² Vikas Bhadoria, Ankur Bhajanka, Kaustubh Chakroborty and Palash Mitra. "India Pharma 2020: Propelling access and acceptance, realising true potential." Mckinsey & Company, 2010

⁵³ Price Waterhouse Cooper. "India Pharma Inc: Capitalising on India's Growth Potential." 2011

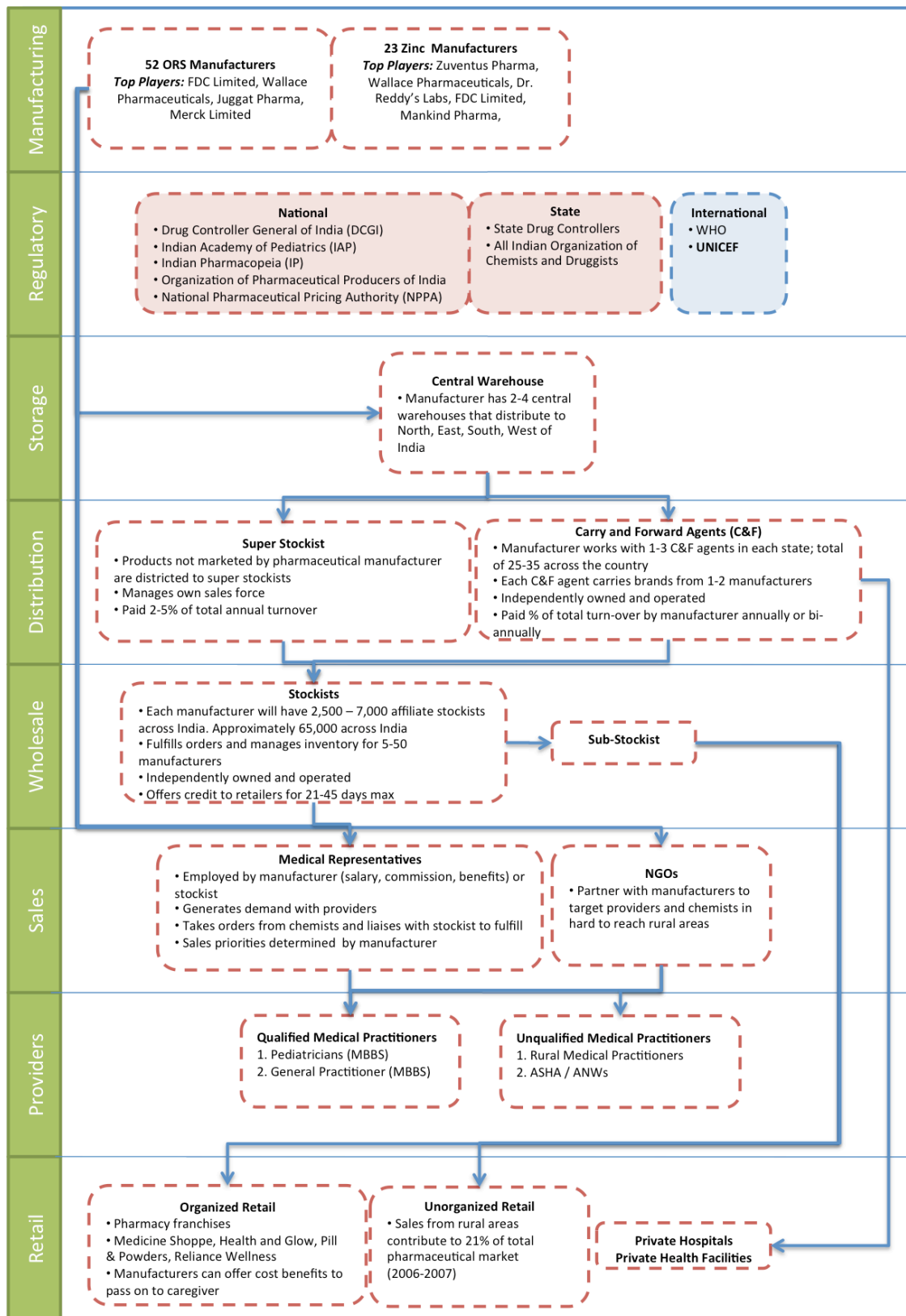


Figure 2: Private sector drug supply chain in India Sources: Eric Langer and Abhijeet Kelkar. "Pharmaceutical Distribution in India." BioPharm International, September 2008; Roger Jeffery et al. "Pharmaceuticals distribution system in India." Centre for International Public Health Policy, July 2007

Regulatory Environment

Key Barriers

- Poor governance structures have led to a largely unregulated private health sector in India, which has led to a large proportion of health delivery provided by unqualified Rural Medical Practitioners (RMPs) and the indiscriminate use of drugs such as antibiotics
- Zinc is not classified as an over-the-counter (OTC) drug, limiting distribution of the product to licensed chemists, direct-to-consumer marketing activities, and a commercially available ORS/zinc co-pack
- ORS and zinc are not included in all the various Standard Treatment Guidelines (STG) for diarrhea treatment, leading to confusion amongst healthcare providers
- Decentralized drug registration has led to the introduction of sub-optimal formulations into the market

Indian Pharmaceutical/Healthcare Regulatory Overview

Providers

India has a highly active private health market, much of which is still unregulated. Though a comprehensive and well-intentioned legal framework has been established to protect patients, enforcing regulations through administrative and bureaucratic controls is limited⁵⁴. In recent years new approaches to regulation have been introduced, including a Consumer Protection Act (1986) and a Right to Information Act (2005), both of which intend to encourage citizen feedback and health delivery through formal channels. The 2002 National Health Policy included *decreasing inequities in health* as one of its principal objectives, and called for greater investment in primary health care and “implementation of statutory regulation” and “monitoring of minimum standards” in the private sector (Government of India, 2002). Despite these efforts, the regulation of prices, quality and quantity of health services in the private sector is not easily achievable, requiring large volumes of skilled human resources and the implementation of complex information technology systems to capture data-driven information⁵⁵.

In some cases, non-state actors have formed to influence professional self-regulation. This includes the **Indian Medical Association (IMA)** and the **Indian Academy of Pediatrics (IAP)**, which are both voluntary organizations that represent the interests of qualified, allopathic healthcare providers in India. Over 200,000 providers have obtained membership with the IMA and IAP, which are organized into three-tier structure: national, state and district. This membership enters individuals into a “social contract” that entails abiding by the organization’s Standard Treatment Guidelines (STG), and offers access to opportunities such as Continuing Medical Education (CME) seminars. Recognizing the strength and influence of these groups, the Government of India (GoI) invites key members to participate in critical appraisals of various state and national health programs^{56,57}.

Though unqualified health providers, which account for 65% of all private sector providers in India⁵⁸, are largely removed from these self-regulation efforts, the difference in the quality of diarrhea treatment between qualified and unqualified providers was found to be marginal in one ethnographic study conducted in New Delhi, India by the World Bank⁵⁹. The authors found that of the unqualified providers observed, only

⁵⁴ David H. Peters and V.R. Muraleedharan. “Regulating India’s Health Services: To what end? What future?” *Social Science and Medicine*, 2008; 66: 2133-2144

⁵⁵ Ibid

⁵⁶ Indian Academy of Pediatrics (IAP). Web. Accessed on October 12, 2011. Available at: <http://www.iapindia.org/about-iap/iap-introduction>

⁵⁷ Indian Medical Association (IMA). Web. Accessed on October 12, 2011. Available at: http://www.ima-india.org/IMA_history.html

⁵⁸ Centre for Policy Research. “Mapping Medical Providers in Rural India: Four Key Trends.” February 2011.

⁵⁹ Jishnu Das, Jeffrey Hammer, and Kenneth Leonard. “The Quality of Medical Advice in Low-Income Countries.” The World Bank Development Research Group, Jan. 2008.

20% completed the essential tasks for diarrhea treatment, in comparison to qualified providers, who were aware of 40% of the essential tasks, but only completed 25% of them. It is important to note that this fares high in comparison to public sector providers, who were aware of 30% of the essential tasks, but only completed 8% of them⁶⁰.

Retailers

Both organized and unorganized pharmacies are represented under the **All India Organization of Chemists and Druggists (AIOCD)**. The association represents and supports 65% of all the pharmacies and stockists in the country⁶¹. Over the years, the organization has gained significant influence over decisions around manufacturer pricing and stocking of new products at the retail level. According to the Centre of Public Health Policy, when a pharmaceutical manufacturer wants to launch a new health product into the market, AIOCD demands cash donations for each state chapter in exchange for an approval letter, otherwise, the health product can be excluded from retailer stock lists⁶². This level of bureaucracy can lead to delays in the launch of new health products and result in manufacturers introducing low profit products in only select high-burden states. Structured interviews with pharmacists and wholesalers revealed that AIOCD is planning to consolidate its members (retailers and stockists) under a common franchised brand to leverage economies of scale for health products, infrastructure, sales and marketing. Though this effort has the potential to strengthen the drug supply chain, improving consistent availability of drugs such as ORS and zinc, it is uncertain if savings will be passed on to the consumer⁶³.

The AIOCD or the GOI do not actively engage in regulating retailers to ensure appropriate treatments are dispensed to patients though misdiagnosis and the overprescription of drugs is common⁶⁴. Though drugs are technically classified under policy schedules that outline whether a prescription for a drug is required or not (see below), studies have shown that any drug can be purchased at the retail level with or without documentation. In particular, this has led to the indiscriminate use of antibiotics for various ailments, including diarrhea, contributing to the increasing risk of antibiotic resistance in the country⁶⁵.

Manufacturers

The **Indian Drug Manufacturing Association (IDMA)** represents the interests of 800⁶⁶ domestic manufacturers by negotiating with the GOI on issues including price control, patents, R&D, quality and GMP and exports. The organization is also involved in revising the Indian Pharmacopeia (IP), which is the primary manual used by pharmaceutical companies for drug standards. Currently, the 2007 and 2010 IPs do not include standards for oral zinc sulphate tablets, which may be limiting widespread knowledge of the technical specifications and broad standardization of this formulation amongst manufacturers⁶⁷.

At the government level, the **Ministry of Chemicals & Fertilisers (MoC&F)** is responsible for drafting pharmaceutical policies in the interest of the private sector and the consumer⁶⁸. Currently, a new drug pricing legislation has been proposed by the MoC&F, which will impact the diarrhea treatment market (see below).

⁶⁰ Jishnu Das, Jeffrey Hammer, and Kenneth Leonard. "The Quality of Medical Advice in Low-Income Countries." The World Bank Development Research Group, Jan. 2008.

⁶¹ All India Organization of Chemists and Druggists (AIOCD). Web. Accessed on October 12, 2011. Available at: <http://www.aiocd.net/>

⁶² Roger Jeffery et al. "Pharmaceuticals distribution system in India." Centre for International Public Health Policy, July 2007

⁶³ Ibid

⁶⁴ David H. Peters and V.R. Muraleedharan. "Regulating India's Health Services: To what end? What future?" *Social Science and Medicine*, 2008; 66: 2133-2144

⁶⁵ Ibid

⁶⁶ Indian Drug Manufacturing Association (IDMA). Web. Accessed on October 13, 2011. Available at: <http://www.idma-assn.org/>

⁶⁷ Gitanjali B, Weerasuriya K. The curious case of zinc for diarrhea: Unavailable, unprescribed, and unused. *J Pharmacol Pharmacother* 2011;2:225-9

⁶⁸ Ministry of Chemicals & Fertilizers, Government of India. Web. Accessed on Dec 10, 2011. Available at: <http://www.fert.gov.in/aboutus/history.asp>

Drug Registration and Classification

The key legislation for pharmaceutical regulation is the Drugs and Cosmetics Act (DCA)⁶⁹ and its subordinate legislation, the Drugs and Cosmetics Rules (DCR)⁷⁰. The Ministry of Health and Family Welfare within the Central Government enforces this legislation and it applies to all imported and domestically manufactured allopathic, ayurvedic and homeopathic medicines. The **Drug Controller General of India (DCGI)** is primarily responsible for approving new drugs, molecules, new usages and claims and clinical research and trials⁷¹. The DCGI also classifies drugs into various schedules to regulate the prices and sales channels through which these drugs can be sold to the consumers. Figure 2 provides an overview of the drug scheduling structure in India.

In terms of diarrhea treatment, the DCGI has classified ORS as Schedule K, or otherwise known as an Over-the-Counter (OTC) drug⁷² (Figure 3). This means that ORS can be purchased at any shop, including licensed pharmacies in India without a prescription and marketed directly to consumers. Marketing activities should follow in line with the ethical guidelines outlined by the “Drugs and Cosmetic Act, 1940”⁷³ and the voluntary code of conduct established by the Organization for Pharmaceutical Producers of India (OPPI), which

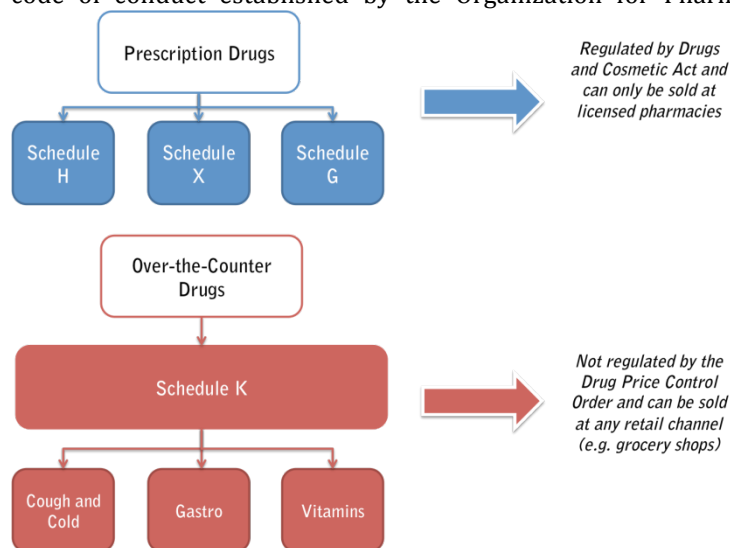


Figure 3: Overview of drug status schedules in India **Source:** Ministry of Health and Family Welfare, Department of Health, Government of India. “The Drugs and Cosmetics Act and Rules, 1940.” Corrected up to April 30, 2003

discourages claims that exaggerate the efficacy of a drug⁷⁴. Zinc, in comparison has not been formally categorized in a drug schedule. Although this discrepancy does not entirely limit the availability of the product at licensed pharmacies⁷⁵, direct to consumer marketing and distribution to non-medical retailers (e.g. grocery stores) is not permitted for zinc until Schedule K status is in place. As a result, demand generation activities for zinc has been limited. For instance, a pilot project led in three districts that aimed to increase access to diarrhea treatment through a distribution network of 70 mobile female entrepreneurs successfully increased ORS sales by 164% from May to July 2009 but could not include zinc in the program due to its ambiguous regulatory status⁷⁶.

In contrast, antibiotics, which are commonly prescribed for diarrhea treatment, are classified as “prescription only,” which means they should only be sold at licensed pharmacies

⁶⁹ Ministry of Health and Family Welfare, Department of Health, Government of India. “The Drugs and Cosmetics Act and Rules, 1940.” Corrected up to April 30, 2003. Available at: <http://cdsco.nic.in/html/copy%20of%201.%20d&cact121.pdf>

⁷⁰ Ministry of Health and Family Welfare, Department of Health, Government of India. “The Drugs and Cosmetics Rules: Conditions of License for Cosmetic Manufacturing, 1945.” Available at: http://www.drugscontrol.org/cond_mfg_cosmetics.pdf

⁷¹ Vijay Bhangale. “OTC Marketing of Drugs.” International Marketing Conference on Marketing & Society, April 8-10, 2007. Available at: <http://dspace.iimk.ac.in/bitstream/2259/347/1/397-402.pdf>

⁷² It is important to note that this drug classification is not the WHO Low-Osmolarity ORS formulation

⁷³ Ministry of Health and Family Welfare, Department of Health, Government of India. “The Drugs and Cosmetics Act and Rules, 1940.” Corrected up to April 30, 2003. Available at: <http://cdsco.nic.in/html/copy%20of%201.%20d&cact121.pdf>

⁷⁴ Organisation of Pharmaceutical Producers of India (OPPI). “OPPI Code of Pharmaceutical Marketing Practices 2010.” Web. Accessed on April 4, 2012. Available at: <http://www.indiaoppi.com/memrfiledat/publications834845dre/OPPI%20Marketing%20Code%202010%20-%20Complete%20-%20Final-Final.pdf>

⁷⁵ Rural Research Institute (SRI). “Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management.” 2008

⁷⁶ Anand Sinha. “Leveraging base of the pyramid entrepreneurs for ORS in India.” USAID, 2010

and to patients with a prescription from a provider. Though the products are commonly sold without a prescription, distribution and availability of the products are widespread, especially in rural areas⁷⁷.

Recently, there has been growing momentum around securing schedule K status for zinc. At a meeting held by the Clinical Development Service Agency (CDSA) and Department of Biotechnology (DBT) in New Delhi, India (*Meeting of Suppliers of zinc Tablets for the Treatment of Childhood Diarrhea*) in August 2011, the DCGI committed to considering Schedule K status of zinc provided the appropriate documentation and evidence was submitted. Since then, various NGOs have made plans to submit formal applications.

While the office of the Drugs Controller General of India (DCGI) is responsible for approving all new molecules and unique new formulations at the central level, it is the Department of Food and Drug Administration (FDA) in every state that has the authority to issue manufacturing and selling licenses to pharmaceutical manufacturers⁷⁸. Interviews with leading pharmaceutical manufacturers and sub contractors revealed that the state FDAs do not usually enforce drug quality regulations with the same intensity as the DCGI and that manufacturers exploit this decentralized registration system to introduce irrational formulations into the market. According to the GOI, approximately 10% of India's total pharmaceutical market is substandard; the WHO's figures are higher⁷⁹. For instance, products that combine ORS and zinc and ORS and Probiotic into a powder formulation have been found on the market, though they have not been clinically tested for efficacy. These inappropriate formulations not only impact consumer confidence in the efficacy of the WHO treatment for diarrhea management, but also threaten the health of children who use the product.

Standard Treatment Guidelines

ORS and zinc have been included and endorsed as the preferred treatments for diarrhea management by various regulatory bodies including the Indian Academy of Pediatrics (IAP) in 2003, the Integrated Management of Neonatal and Childhood Illnesses (IMNCI) strategy, the National Rural Health Mission (NRHM) commodities list, and the National Program for Treatment for Diarrhea in 2007⁸⁰. However, according to the World Health Organization (WHO), this directive has not been unanimously adopted across "official" policy documents in India, leading to confusion amongst stakeholders such as providers, non-profit organizations and government personnel about the appropriate treatment for diarrhea⁸¹. Firstly, the 2011 National Essential Medicines List only includes the syrup formulation of zinc. Secondly, the Indian Pharmacopeia (IP) 2007 and 2010 and National Formulary of India (NFI) 2010 does not include oral zinc sulfate. Lastly, the Standard Treatment Guidelines (STG) brought out by the Armed Forces Medical College, Pune, in collaboration with Ministry of Health and Family Welfare, GOI, does not list zinc as a treatment for diarrhea management⁸². The lack of consistent alignment on the appropriate treatment for diarrhea undermines efforts to significantly scale up zinc and ORS.

Drug Price Control Order

The pharmaceutical market in India is extremely price-sensitive, and is considered to be one of the most price-controlled in the world⁸³. The price of drugs are established in one of two ways in the country. The first is when the Drug Price Control Order (DPCO) identifies an active pharmaceutical ingredient (API) that has a large market size (between ~ \$USD 200,000 – 800,000 market), but is dominated by one player (single formulation owning 90% market share or more). This type of API becomes classified as a "scheduled drug"

⁷⁷ Anita Kotwani and Kathleen Holloway. "Trends in antibiotic use among outpatients in New Delhi, India," *BMC Infect Dis.* 2011; 11: 99.

⁷⁸ Vijay Bhangale. "OTC Marketing of Drugs." International Marketing Conference on Marketing & Society, April 8-10, 2007. Available at: <http://dSPACE.iimk.ac.in/bitstream/2259/347/1/397-402.pdf>

⁷⁹ Alla Katsnelson. "Substandard drugs overshadowed by focus on fakes," *Nature Medicine*, 2010; 16:364

⁸⁰ Gitanjali B, Weerasuriya K. The curious case of zinc for diarrhea: Unavailable, unprescribed, and unused. *J Pharmacol Pharmacother* 2011;2:225-9

⁸¹ Ibid

⁸² Gitanjali B, Weerasuriya K. The curious case of zinc for diarrhea: Unavailable, unprescribed, and unused. *J Pharmacol Pharmacother* 2011;2:225-9

⁸³ Anita Kotwani, and Libby Levison. "Price Components and Access to Medicines in Delhi, India." Department for International Development (DFID), April 2007.

and is subject to a pricing formula to establish its Maximum Retail Price (MRP)⁸⁴. Currently, there are 76 out of 500 APIs that fall into this category, which includes 37 of the the 348 drugs on the National List of Essential Medicines (NLEM). Of these 37 drugs, three are common antibiotics, ciprofloxacin, metronidazole, and norfloxacin, which are sometimes inappropriately prescribed/utilized for diarrhea treatment. For all other drugs, called “non-scheduled,” manufacturers set the MRP and register the price with the NPPA; prices can be raised by a 10% maximum each year⁸⁵.

Maximum drug margins established by the NPPA		
	Scheduled Drugs	Non-scheduled Drugs
Wholesaler	8% on the maximum retail price	10% on the maximum retail price
Retailer	16% on the maximum retail price	20% on the maximum retail price

Table 2: Overview of maximum margins established by NPPA for scheduled and non-scheduled drugs *Source:* Eric Langer and Abhijeet Kelkar. “Pharmaceutical Distribution in India.” BioPharm International, September 2008.

The formula for scheduled drugs defines the maximum mark-ups for wholesalers and retailers, which is 8% and 16%, respectfully. Though not legally mandated, the average mark-up for non-scheduled drugs is 10% for wholesalers and 20% for retailers⁸⁶ (Table 2).

All drugs are subject to a 16% excise duty levied by the government on 57.5% of the MRP, in addition to a 3% tax used to improve education in India. At each level of the supply chain, drugs are taxed an additional 4% (VAT). However, at each level taxed, VAT is refunded to the previous level with the exception of the final point of sale in the public and private sectors, which negatively impacts procurement volumes and consumer affordability⁸⁷.

The National Pharmaceutical Pricing Authority (NPPA) manages the enforcement of the policy by monitoring drug prices of scheduled drugs using IMS data. However, the WHO has recently expressed disapproval of this process, stating that while IMS volume data is accurate, its pricing data does not take into account “discounts, rebates, and bundling deals” since the data is collected at the wholesaler level⁸⁸.

In 2007, the Department for International Development (DFID), United Kingdom, conducted a drug pricing study in New Delhi, India to examine the level of enforcement of the DPCO⁸⁹. The author investigated the pricing of three scheduled drugs, Ciprofloxacin, Ranitidine and Salbutamol, and found that two had wholesale margins close to the mandated 8%. Antibiotic, ciprofloxacin, on the other hand, was found to have a margin of 11%. Retail margins were much higher than the prescribed 16% maximum, especially for branded-generics not marketed by manufacturers, ranging from 92-436%. Margins at the wholesale level for non-scheduled drugs studied were found to align with the unofficial maximum mark-up (10%). However, similar to scheduled drugs, there was a wide range in margins at the retail level, with non-scheduled branded generics having higher margins than non-scheduled branded drugs⁹⁰.

⁸⁴ Ibid

⁸⁵ Anita Kotwani, and Libby Levison. “Price Components and Access to Medicines in Delhi, India.” Department for International Development (DFID), April 2007.

⁸⁶ Eric Langer and Abhijeet Kelkar. “Pharmaceutical Distribution in India.” BioPharm International, September 2008.

⁸⁷ Anita Kotwani, and Libby Levison. “Price Components and Access to Medicines in Delhi, India.” Department for International Development (DFID), April 2007.

⁸⁸ Lynne Taylor. “WHO warns India over drug pricing data,” Pharma Times, January 17, 2012. Web. Accessed on February 10, 2012. Available at: http://www.pharmatimes.com/Article/12-01-17/WHO_warns_India_over_drug_pricing_data.aspx

⁸⁹ Anita Kotwani, and Libby Levison. “Price Components and Access to Medicines in Delhi, India.” Department for International Development (DFID), April 2007.

⁹⁰ Ibid

The range in margins is largely determined by if a drug is marketed or not. Products that are not marketed are sold at a much lower rate to wholesalers (i.e. super stockists, stockists, sub-stockists), who in turn sell to pharmacies/retail shops. Promotion, in these cases, is the responsibility of the super-stockist or retailer. If a product is marketed, the cost of promotion will either be absorbed by the pharmaceutical manufacturer, across the supply chain or passed on to the consumer⁹¹. Manufacturing costs, in contrast, play less of a role in determining the MRP of a drug.

In the case of diarrhea treatment, most leading ORS brands on the market are not actively promoted, and margins across the supply chain for a small sachet are estimated to range from 75% - 533%. This data was drawn from two sources; firstly, the Tamil Nadu Government procures a small sachet of ORS for \$USD 0.032⁹² and secondly, non-profit pharmaceutical company LOCOST sells a small sachet of ORS for \$USD 0.08⁹³. The range in retail prices for one small sachet of ORS (4.4-5g) is between \$USD 0.07 - 0.10. The range in retail prices for one large sachet of ORS (~20g) is between USD \$0.20 - \$0.35⁹⁴.

Interviews with three leading zinc manufacturers illustrated a variation in promotion activities from limited investment to significant investment during the diarrhea season, to those who received marketing subsidies from international aid donors. One manufacturer that invests in marketing activities during the diarrhea season reported absorbing the cost of promotion, taking a 15% margin, versus a 30% margin and thus not impacting the margins available across the supply chain. Though the manufacturing cost of zinc was unable to be obtained from key informants, Tamil Nadu government procures 100 tablets of zinc sulphate for \$0.27, which can be considered one data point for the possible manufacturing cost of zinc sulphate⁹⁵. Retail prices for 10 tablets of zinc sulphate range from \$0.45 - \$0.65⁹⁶.

National Pharmaceutical Pricing Policy

The DPCO was established in India in 1979 to correct market failures and ensure accessibility to treatment, initially controlling the price of over 300 bulk drugs. Over the years, however, the policy has increasingly been dismantled with fewer drugs being controlled and pharmaceutical companies avoiding price controls by making minor adjustments to the formulation of drugs on the scheduled list. These circumstances have led to discord between consumer organizations such as the All India Drug Action Network (AIDAN) and pharmaceutical industry interest groups such as the Indian Pharmaceutical Alliance (IPA); the latter urging the DPCO to expand the number of scheduled drugs to include all those on the NLEM, which includes ORS and zinc, and the former arguing that there is enough competition (20,000 companies; 60,000 brands) for prices to be modulated by the market itself.

Since 2011, however, a new drug pricing legislation, drafted by the Department of Pharmaceuticals within the Ministry of Chemicals and Fertilizers, GOI, called the "National Pharmaceuticals Pricing Policy (NPPP) 2011" is under review by the Indian Supreme Court. The new policy proposes to regulate the prices of all 348 drugs on the 2005 NLEM and others added to the 2011 NLEM by setting a ceiling price for each drug. This ceiling price would be calculated by taking the weighted average price of the three leading brands of the drug. If the policy is finalized, nearly 75% of the domestic Indian pharmaceutical market will be under price control (1,154 drugs and 6,441 formulations), leading to an estimated revenue loss of \$USD 600 billion⁹⁷.

Public interest groups have expressed concerns with the proposed policy. The AIDAN has filed a Public Interest Litigation (PIL) against the NPPP, claiming that the pricing methodology will lead to increased prices

⁹¹ Interviews with pharmaceutical manufacturers, October 2011

⁹² Gitanjali B, Weerasuriya K. The curious case of zinc for diarrhea: Unavailable, unprescribed, and unused. *J Pharmacol Pharmacother* 2011;2:225-9

⁹³ LOCOST India. "Price List," 2011. Available at: <http://www.locostindia.com/>

⁹⁴ AED. "ORS Producers Matrix." Updated September 16, 2011

⁹⁵ Gitanjali B, Weerasuriya K. The curious case of zinc for diarrhea: Unavailable, unprescribed, and unused. *J Pharmacol Pharmacother* 2011;2:225-9

⁹⁶ AED. "Zinc Producers Matrix." Updated September 16, 2011

⁹⁷ Lynne Taylor. "Indian drugmakers urge government over price controls," *Pharma Times*, December 8, 2011. Web. Accessed on February 10, 2012. Available at: http://www.pharmatimes.com/Article/11-12-08/Indian_drugmakers_urge_govt_over_price_controls.aspx

of some essential medicines since market leaders are often the highest priced products. The Indian Pharmaceutical Alliance (IAP) warns that regulation of the new policy will be “ineffective and unwieldy” and lost revenue may result in reduced capacity to invest in domestic drug innovation. The GOI contests that revenues will be recovered through increased spending in public procurement of drugs, from 0.1% to 0.5% of India’s Gross Domestic Product (GDP) and centralization of the procurement system⁹⁸.

If the policy passes, the diarrhea treatment market will be impacted. ORS, zinc and common antibiotic, ciprofloxacin are on the NLEM. Though the retail prices of ORS and zinc are not expected to rise, since the range between highest and lowest price is minimal, prices of alternative diarrhea treatments not on the NLEM, such as ofloxacin-ornidazole, loperamide, and racecadotril, could rise to recover revenue losses.

⁹⁸ Lynne Taylor. “India plans to price control 60% of pharma market,” Pharma Times, November 1, 2011. Web. Accessed on February 10, 2012. Available at: http://www.pharmatimes.com/Article/11-11-01/India_plans_to_price-control_60_of_pharma_market.aspx

Manufacturing

Key Barriers

- The ORS and zinc market is dominated by five companies that invest limited resources in the sales, marketing and expanded distribution of the products
- ORS and zinc compete with common, high-margin, alternative diarrhea treatment products including antibiotics and anti-diarrheals. Increasing uptake of ORS and zinc will require product displacement
- ORS and zinc are considered low priority products for pharmaceutical companies due to perceived low consumer demand, and competing priorities

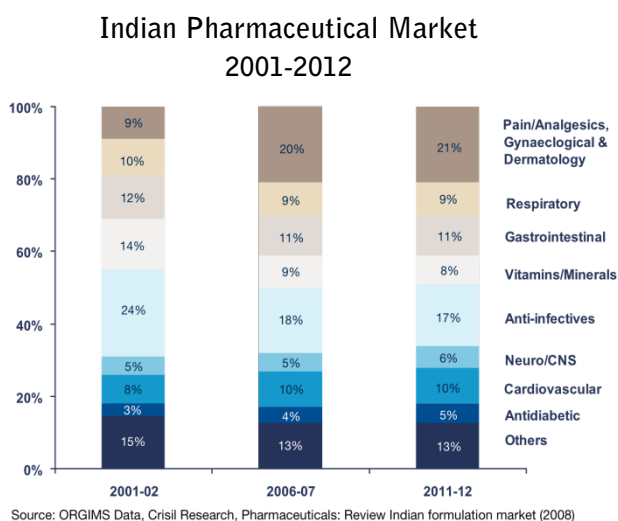


Figure 4: Overview of India's Pharmaceutical Market

India, in order of largest market share, were: Cipla, Ranbaxy, GSK India, Piramal Healthcare, Sun Pharma, Zydus Cadila, Alkem Labs, Pfizer India, Mankind Pharma, and Abbott. Increasingly, multinational pharmaceutical companies are interested in the India pharma market to establish strategic partnerships and licensing deals, and consider acquisition opportunities. Between April 2000 and April 2010, the Indian pharma industry attracted US\$1707.52 million worth of foreign direct investment⁹⁹.

Treatments used for diarrhea fall under the gastrointestinal, anti-infective, vitamins/minerals and other therapeutic groups, which together account for 48% of the Indian pharmaceutical market. This includes ORS, zinc, anti-diarrheals, antibiotics, probiotics and ayurvedic products, which are collectively manufactured by 270 companies in India. In September 2011, the Moving Average Total (MAT) of the diarrhea treatment market for adult and pediatric populations was valued at US\$260 million, of which 15 companies controlled 60% of the market. Antibiotics are the largest therapeutic segment in the diarrhea treatment market,

There are over 20,000 pharmaceutical manufacturers in India, of which approximately 200 companies control 70% of the market⁹⁹. In 2010, the top pharmaceutical companies in

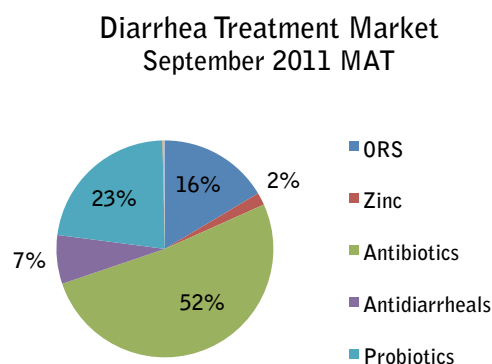


Figure 5: Overview of Diarrhea Treatment Market in India
Source: ORG/IMS Data, September 2011 MAT

⁹⁹ Ministry of Industry Department of Commerce, Government of India. "Strategy for increasing exports for pharmaceutical products: Report of Task Force." December 2008

¹⁰⁰ Vikas Bhadoria, Ankur Bhajanka, Kaustubh Chakroborty and Palash Mitra. "India Pharma 2020: Propelling access and acceptance, realising true potential." Mckinsey & Company, 2010

accounting for over 50% of the total annual revenue, which is double the value of ORS and zinc combined¹⁰¹. Nearly 60-80% of annual sales for diarrhea treatments are generated between March and July, during the monsoon season in India¹⁰².

Interviews with leading diarrhea treatment pharmaceutical manufacturers indicated that ORS and zinc are considered low-to-medium priority products¹⁰³. Many companies entered the ORS and zinc market at the request of the GOI and IAP when the WHO revised its diarrhea management guidelines in the 1980s and again in 2004¹⁰⁴. Other manufacturers produce ORS and zinc to offer providers with a “complete diarrhea management” solution, which also includes anti-diarrheals and probiotics. Since then, increases in middle-class wealth and changes in the Indian disease profile have shifted internal priorities towards higher-margin chronic disease therapeutic segments. Companies that manufacture ORS and control a substantial share of the market consider the products “cash cows,” and thus invest limited resources into sales and marketing. Zinc, on the other hand, is considered a new opportunity for the leading manufacturers in the market, though commercial marketing has been limited due to the current drug classification of the product. The following outlines the market dynamics for each diarrhea treatment product categories in more detail.

Oral Rehydration Salts

Market Size: In September 2011, the MAT for the ORS market in India was estimated to be worth approximately \$US37 million. In the same period, 214 million units of ORS were sold nationally¹⁰⁵. By 2015, the ORS market for pediatric diarrhea alone has the potential to reach approximately \$US67 million¹⁰⁶.

Market Share: There are 52 pharmaceutical manufacturers of ORS in the Indian market. Pharmaceutical company FDC Limited is the industry leader of ORS, both in terms of market share and the number of formulations/brands available. Its cornerstone product, Electral, accounts for 53% of all ORS units sold in India and in some regions has become a generic trademark (Figure 6). The product’s top market position has led to a long tail of additional brands and formulations. However, due to its existing position in the market, the company engages in limited marketing activities and is focused on expanding its 50-country export portfolio. Other ORS manufacturers, in order of largest market share, include: Wallace Pharmaceuticals, Juggat Pharma and Merck Limited¹⁰⁷.

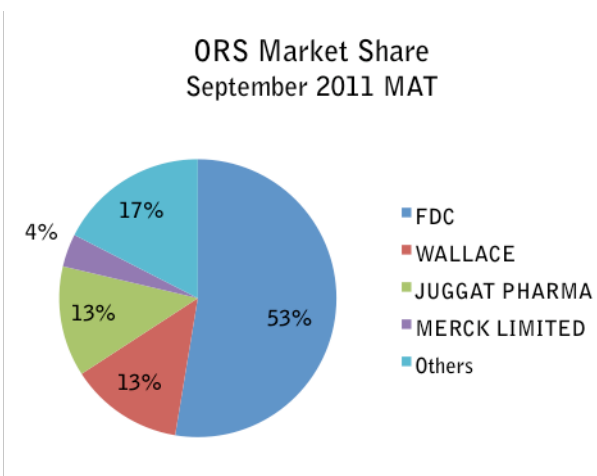


Figure 6: ORS Market Share by Pharmaceutical Manufacturer in India
Source: ORG/IMS Data, September 2011 MAT

¹⁰¹ ORG/IMS Data, September 2011. *The data collection methodology utilized by ORG/IMS does not allow for a distinction between the market for pediatric and adult diarrhea treatments

¹⁰² Interviews with pharmaceutical manufacturers, October 2011

¹⁰³ Ibid

¹⁰⁴ ICICI Foundation and USAID India. "Saathi Bachpan Ke: Promoting Diarrhea Management through the Private Sector in Urban North India." 2008

¹⁰⁵ ORG/IMS Data, September 2011

¹⁰⁶ Based on treatment of 80% of US pediatric diarrhea episodes in India with two 20g ORS sachets at a manufacturer selling price of \$0.086. *Incidence rate source:* Boschi-Pinto C, Lanata CF, Black RE (2009) The Global Burden of Childhood Diarrhea. *Maternal and Child Health* (J.E. Ehiri (ed.), 225-43. *Pricing data source:* MSH International Drug Indicator Guide, 2010

¹⁰⁷ ORG/IMS Data, September 2011

Formulations: There are four types of ORS formulations: powder, liquid, tablet and drops (Table 3). Powder sachets are the leading type of formulation in the market, with 50 manufacturers producing the product (See Table 3). Though some manufacturers expressed that caregivers have been found to prefer pre-made liquid

Formulation	Number of Manufacturers	Number of Brands	Total units (Sept 2011 MAT)	Market Share (%)
Powder	45	61	173,609,000	78.5
Liquid	18	23	40,443,000	18.3
Tablet	2	2	43,000	0.02
Drops	1	1	1,000	0
Total	52	87	214,096,085	100

Table 3: Overview of ORS market in India. Source: ORG/IMS, September 2011 MAT

formulations due to the lack of access to clean water, the product is increasingly being discontinued due to high storage and distribution costs¹⁰⁸. In 2004, when the WHO treatment guidelines were revised to low-osmolarity ORS, the

Government of India, IAP and USAID encouraged leading manufacturers to switch to the new formulation. Though the total number of manufacturers currently producing L-ORS is unavailable, companies FDC, Wallace and Merck Limited, which account for 70% of the market, all switched to the L-ORS formulation in 2007 under the Saathi Bachpan Ke program led by USAID¹⁰⁹.

To differentiate ORS in the crowded marketplace, manufacturers have introduced a range of flavors and innovative types of packaging. For instance, pharmaceutical manufacturer, Dr. Reddy's Laboratories and RPG Life Sciences sells five sachets of orange-flavored ORS in a 200ml tumbler for easy measuring and administration. Products mixing ORS with probiotic or zinc have been found on the market, though these products have not been supported by clinical evidence to date. An undisclosed manufacturer is currently conducting R&D on a tablet ORS formulation.

Sales and Marketing: Pharmaceutical manufacturers do not typically invest in sales and marketing activities for ORS. Given the product's long-standing history in India, and high awareness amongst public and private providers,¹¹⁰ detailing activities are not common, or considered high impact relative to detailing for other higher-margin products. That said, during the diarrhea season (March-July), some manufacturers will offer providers and retailers trade schemes for ORS, such as "buy 10, get 1 free." Every year, the IAP organizes "ORS week" during the monsoon season to remind its members, mostly qualified providers, to prescribe ORS. Each year, a specific message is emphasized through CMEs and community events, encouraging the use of zinc with ORS, and discouraging the use of antibiotics for diarrhea treatment. Pharmaceutical manufacturers often support the IAP with free samples to distribute during ORS week¹¹¹. Between 2002-2005, a public-private partnership between USAID and ICICI Foundation, the GOI, McCann Healthcare and nine pharmaceutical manufacturers, launched a social marketing campaign in the urban areas of North India to introduce and encourage adoption of the new L-ORS formulation introduced into the WHO guidelines in 2004. Through the use of diverse mass media channels (i.e. television, radio, print), provider detailing, and community-based interpersonal activities such as street theater, the use of L-ORS increased from 25% to 45% in urban areas and 59% to 88% in urban slums. Sales of ORS grew by 10% annually for the duration of the project.

¹⁰⁸ Interviews with pharmaceutical manufacturers, October 2011

¹⁰⁹ ICICI Foundation and USAID India. "Saathi Bachpan Ke: Promoting Diarrhea Management through the Private Sector in Urban North India." 2008

¹¹⁰ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

¹¹¹ Interviews with pharmaceutical manufacturers, October 2011

Zinc Market Share September MAT

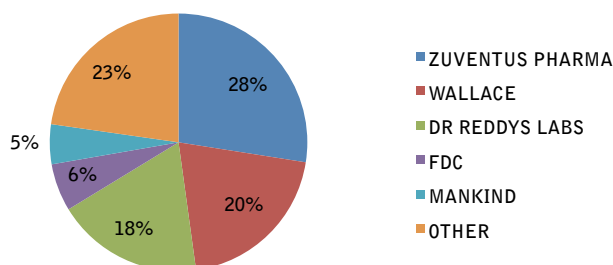


Figure 7: Zinc Market Share by Pharmaceutical Manufacturer in India Source: ORG/IMS Data, September 2011 MAT

Market Size: In September 2011, the MAT for the zinc market was estimated to be worth approximately \$US4.2 million¹¹². In the same month, approximately 7 million units of zinc were sold nationally. According to one leading pharmaceutical manufacturer, the zinc market is experiencing between 20-25% year-over-year growth. Similar to ORS, there is vast potential for growth in this market given the high number of diarrhea incidences in India and the current low uptake rates (<2%). The market for zinc for pediatric diarrhea alone can reach up to US\$61 million by 2015¹¹³.

Market Share: There are 23 manufacturers of zinc in India, with five companies controlling nearly 80% of the market. This includes, in order of market share: Zuventus Healthcare, Wallace Pharmaceuticals, Dr. Reddy's Laboratories, FDC and Mankind Pharma¹¹⁴.

Wallace Pharmaceuticals, Dr. Reddy's Laboratories, FDC and Mankind Pharma¹¹⁴.

Formulations: Manufacturers are producing four types of zinc formulations: syrup, powder suspension and dispersible and non-dispersible tablet formulations (Table 4). In general, caregivers prefer the syrup formulation since water is not required for preparation¹¹⁵. Accordingly, syrups account for 80% of the market¹¹⁶. Similar to ORS, flavored zinc has been introduced to mask the traditionally bitter taste of the product and increase acceptability by caregivers and children.

Formulation	Number of Manufacturers	Number of Brands	Total units (Sept 2011)	Market Share (%)
Syrup	19	19	5,747,140	81.3%
Tablet	12	12	1,314,350	18.6%
Total	23	31	7,061,490	100

Table 4: Overview of zinc market in India. Source: ORG/IMS, September 2011 MAT

Sales and Marketing: Certain leading pharmaceutical manufacturers in the zinc market view the product as an opportunity to refresh the diarrhea treatment market, and are investing resources in sales and marketing activities targeting providers. Interest in the zinc market began in 2006, at the request of IAP and following the inclusion of zinc in the NLEM at the end of 2007¹¹⁷. For others, manufacturing zinc is part of a broader strategy aimed at marketing a complete "diarrhea management solution" to caregivers and providers, which can include ORS, zinc, a probiotic and, in some cases, an anti-diarrheal¹¹⁸.

¹¹² ORG/IMS Data, September 2011

¹¹³ Based on treatment of 50% of U5 pediatric diarrhea episodes in India with ten 20mg zinc dispersible tablets at a manufacturer selling price of \$0.031 per tablet. Incidence rate source: Boschi-Pinto C, Lanata CF, Black RE (2009) The Global Burden of Childhood Diarrhea. Maternal and Child Health (J.E. Ehiri (ed.), 225-43. Pricing data source: MSH International Drug Indicator Guide, 2010

¹¹⁴ ORG/IMS Data, September 2011

¹¹⁵ Interviews with pharmaceutical manufacturers, October 2011

¹¹⁶ ORG/IMS Data, September 2011

¹¹⁷ ICICI Foundation and USAID India. "Saathi Bachpan Ke: Promoting Diarrhea Management through the Private Sector in Urban North India." 2008

¹¹⁸ Interviews with pharmaceutical manufacturers, October 2011

Promotion of zinc by manufacturers includes provider-detailing activities during the diarrhea season with national sales forces ranging between 250 – 800 people, though mostly limited to qualified providers in Class 1 and Class 2 towns (>100,000 people). Manufacturers also reported participating at various conferences to promote zinc, and partnering with NGOs to expand distribution to rural areas. Innovative approaches are being pursued to change prescribing behavior such as partnering with IAP to publish a magazine called “Zinconia Times” for members and offering free samples to patients when they exit provider offices¹¹⁹. In general, marketing and sales efforts have primarily targeted providers, versus direct to consumers, given the current ambiguity of zinc’s regulatory status.

Box 1: Introducing zinc into the Indian market

A leading manufacturer describes the process taken to introduce zinc into the Indian market and influence provider prescription of the product. Although the company is experiencing 20-25% growth in YOY sales of zinc, the company believes that reinforcing consistent messaging to providers for the next 3-5 years is required for the zinc market to achieve its growth potential.

Step 1: Medical Representatives (MRs) targeted high prescribing providers with information about zinc, which included academic literature and flip charts illustrating the clinical efficacy of the product. This information was supplemented with incentives such as free samples, brand reminders (i.e. pens, prescribing pads), and knowledge grants. In general, a maximum of 10 minutes was spent with a provider on a detailing visit.

Step 2: Once the targeted provider agreed to prescribe zinc, the MR visited nearby and/or affiliated retailers and informed them of the provider’s willingness to prescribe the product. Zinc was then offered to the retailer on credit for a trial period to validate demand from providers.

Step 3: Following the initial dissemination of information to providers and product supply to retailers, MRs conducted frequent retail audits to verify that the provider was prescribing zinc. If behavior change was not observed, MRs continued to detail providers using alternative tactics and product messaging, until consistent demand was generated.

Step 4: MRs facilitate a larger order of zinc between the retailer and stockist, leading to increased and consistent availability of the product

Antibiotics

Market Size: The market size for antibiotics used for gastrointestinal treatment, which includes diarrhea, was valued at US\$115.6 million over the period of September 2010 to September 2011¹²⁰. Approximately 202 million units were sold during this period.

Market Share: There are 269 manufacturers of antibiotics for gastrointestinal diseases in India, of which the top 10 companies account for 60% of the market. Leading manufacturers Mankind Pharma, Medley Pharma, Cipla, Stancare and Ranbaxy produce on average 11 different types of antibiotics.

Leading Manufacturers in Gastrointestinal Antibiotics Market
September 2011 MAT

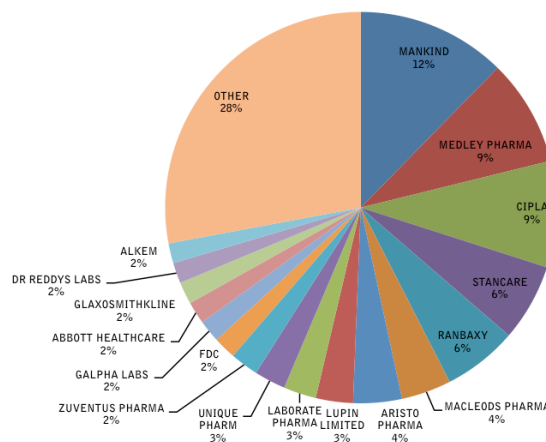


Figure 8: Antibiotic Market Share by Pharmaceutical Manufacturer in India Source: ORG/IMS Data, September 2011 MAT

¹¹⁹ Interviews with pharmaceutical manufacturers, October 2011

¹²⁰ Limitations in the data collection methodology precludes analysis of the % of antibiotics sold that are inappropriately used for diarrhea treatment in India

Antibiotics Market (For Diarrhea Treatment) September 2011 MAT

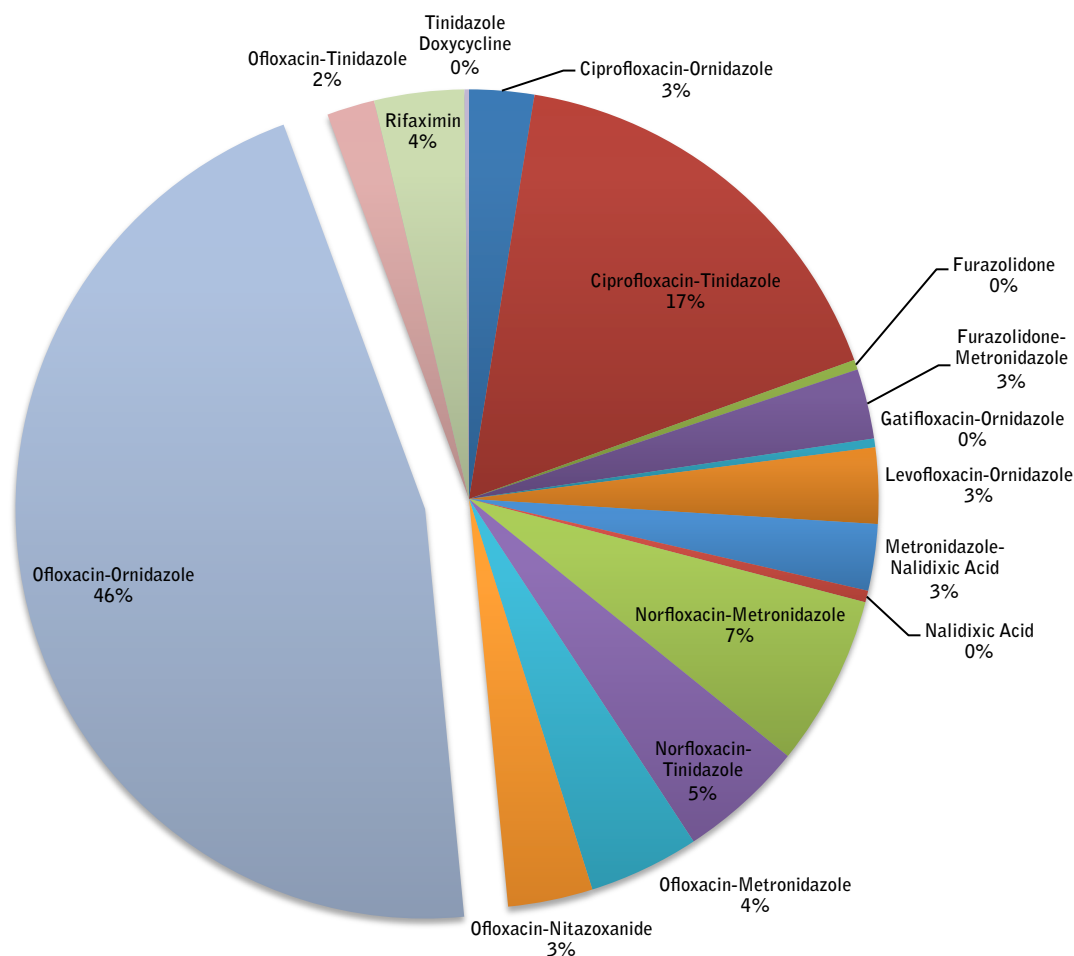


Figure 9: Market share by types of antibiotics in India Source: ORG/IMS Data, September 2011 MAT

Formulations: Sixteen types of antibiotics were included in the September 2011 MAT dataset on the diarrhea treatment market from ORG-IMS, though it is uncertain if this list is exhaustive. Antibiotics are available in three different formulations (solid, liquid, injection). Antibiotics, Ofloxacin-ornidazole and Ciprofloxacin-tinidazole, both in solid formulation, account for 50% of the market. Ofloxacin-ornidazole and Ciprofloxacin-tinidazole have the highest number of manufacturers producing the product in the gastrointestinal market; 134 for the latter and 185 for the former. In general, the solid formulation of antibiotics is preferred (73%) in comparison to liquid (22%) and injection (4%).

A study conducted by market research firm, MART, in three districts in Uttar Pradesh and two districts in Gujarat similarly found Ofloxacin-ornidazole, in addition to Norflox as the most common antibiotic prescribed by Rural Medical Practitioners (RMPs) surveyed. Qualified providers, on the other hand, prescribed a range of antibiotics including Metronidazole, Ofloxacin, Co-trimoxazole, Norfloxacin, Tinidazole, Furazolidone and Ofloxacin-Metronidazole¹²¹.

¹²¹ MART. "Formative research for developing communication strategy to private sector diarrhea alleviation through Zinc & ORS therapy (DAZT)." Submitted to AED Arts. 2011

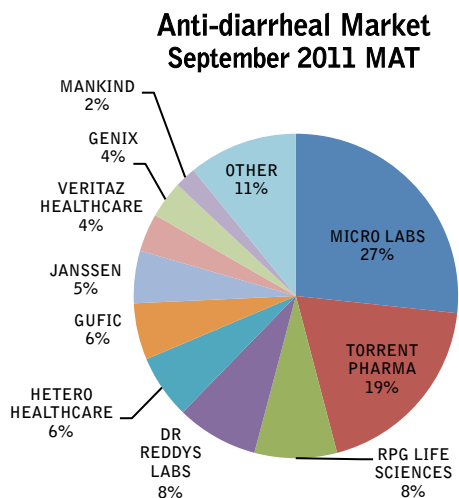


Figure 9: Anti-diarrheal Market Share by Pharmaceutical Manufacturer in India Source: ORG/IMS Data, September 2011 MAT

Market Share: There are 56 manufacturers that produce anti-diarrheals in India, 9 of which control 85% of the market. Though leading ORS and zinc manufacturers, FDC, Wallace, Juggat Pharma, Wallace Pharmaceuticals and Zuventus Healthcare have an anti-diarrheal drug as part of its portfolio, only Dr. Reddy's Laboratories has gained significant market share in this category (8%). Almost all manufacturers were found to produce either Loperamide or Racecadotril, with the exception of Micro Labs, Cipla, Janssen Pharmaceuticals, and Torrent Pharmaceuticals. Micro Labs

leads in sales of Loperamide and Torrent Pharmaceuticals and Dr. Reddy's lead in sales of Racecadotril. Pharmaceutical company, RPG Life Sciences, is the sole producer of anti-diarrheal Lomotil, which is popularly used in the United States of America.

Anti-diarrheals

Market Size: The market size for drugs classified as anti-diarrheals by ORG/IMS was valued at USD\$16 million for the period of September 2010 to September 2011. Approximately 83 million units of anti-diarrheals were sold. This diarrhea treatment category includes Loperamide, an opioid drug that reduces intestinal motility, and Racecadotril, an acetorphan that has an antisecretory effect on the intestine. Loperamide is strictly not recommended for children, and since 1980 the WHO has issued a warning to doctors in low-resource settings to not use Imodium for diarrhea treatment, since it can paralyze a child's intestines¹²². A small randomized control trial found that racecadotril significantly reduces the duration and volume of diarrhea in children when used in conjunction with ORS, but to date, the WHO has not adopted this drug into its guidelines¹²³ and physicians have questioned the validity of the results¹²⁴.

Types of Anti-diarrheals in the India market September 2011 MAT

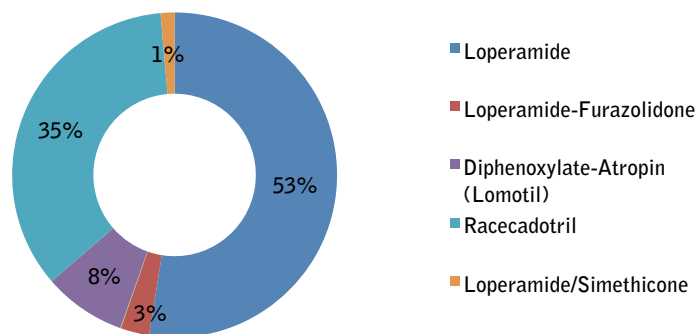


Figure 10: Market share by types of anti-diarrheals in India Source: ORG/IMS Data, September 2011 MAT

¹²² National Cancer Institute, National Institutes of Health. Web. Accessed on January 3, 2012. Available at: <http://www.cancer.gov/drugdictionary?CdrID=41911>

¹²³ Salazar-Lindo E, Santisteban-Ponce J, Chea-Woo E, Gutierrez M. Racecadotril in the treatment of acute watery diarrhea in children. N Engl J Med 2000; 343: 463-467.

¹²⁴ Bhan MK. Racecadotril. Is There Enough Evidence to Recommend it for Treatment of Acute Diarrhea- Editorial. Indian Pediatr 2004; 41: 1203-1204.

Formulations: Anti-diarrheal, Loperamide is the leading drug in this category, with volumes almost double that of Racecadotril. The drugs in a solid formulation (80%) are preferred in the market, in comparison to a powder sachet (20%). Loperamide combined with antibiotics, such as Loperamide-Furazolidone and Loperamide-Metronidazole, are also available.

Sales and Marketing: Key informants from leading pharmaceutical companies confirmed that anti-diarrheals, such as Loperamide or Racecadotril are generally included in the “complete diarrhea management” solution marketed to providers. Specific details on trade schemes for this drug category are unknown.

Probiotics

Market Size: The market for probiotics in India was valued at \$US51 million during the period of September 2010 to September 2011. Approximately 139 million units were sold nationally. According to a 2009 report by Frost & Sullivan, the probiotics market in India is expected to grow at a CAGR of 20-25% until 2015¹²⁵.

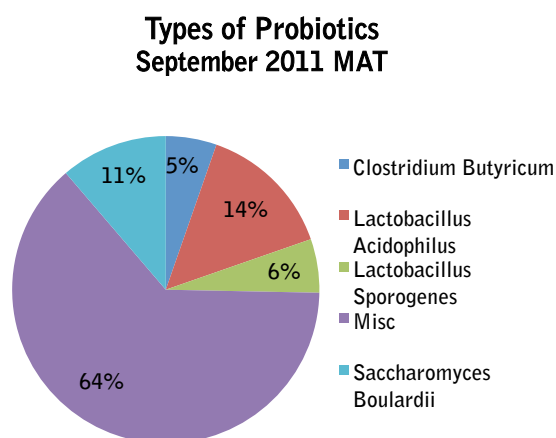


Figure 11: Market share by types of probiotics Source: ORG/IMS Data, September 2011 MAT

Probiotics are strains of beneficial bacteria that help maintain intestinal balance. The human gut is home to millions of beneficial bacteria, but these are often depleted due to chronic usage of antibiotics, junk food or ailments such as diarrhea and indigestion. Ingesting probiotics allows the body to maintain beneficial bacteria and prevent future episodes of intestinal diseases¹²⁶.

Market Share: There are 83 manufacturers in the probiotic market in India, of which the top five companies control just over 50% of the market. This includes: Sanofi Aventis, USV, Dr. Reddy’s Labs, Uni Sankyo and Tablets India. Similar to anti-diarrheals, leading ORS and zinc manufacturers Merck Limited, FDC, Wallace Pharmaceuticals and Mankind Pharma produce probiotic products, but are not top players. Further, probiotic products are often imported into India¹²⁷; suggesting the increasing necessity to offer the product as part of the diarrhea treatment therapy basket to remain competitive.

Formulations: Four main types of probiotics account for 40% of the market. These include, in order of market share: lactobacillus acidophilus, saccharomyces boulardii, lactobacillus sporogenes, and clostridium butyricum. Probiotics are most commonly sold in a solid formulation (57% of sales), though powder sachets (29%) and liquid (14%) are also available.

Sales and Marketing: A leading manufacturer is using the tag line, “rehydrate, replenish and refuel” to market its ORS, zinc and probiotic products as the “complete diarrhea management solution”.

Diarrhea Treatment Market Outlook

Leading pharmaceutical manufacturers are bearish on the scope for significant growth in the diarrhea treatment market. Though zinc is viewed as an opportunity to revive the diarrhea treatment market, manufacturers believe it will take between 5-7 years of consistent messaging and promotion, increased government commitment, public-private partnerships and a change in the regulatory status of the product to broadly and sustainably shift caregivers from deeply entrenched diarrhea treatment behaviors, such as home

¹²⁵ Frost & Sullivan. “New Product Innovation: Probiotics and Nutraceuticals.” November 30, 2011

¹²⁶ Ibid

¹²⁷ Interviews with pharmaceutical manufacturers, October 2011

solutions and antibiotics, to zinc. If this can happen, manufacturers believe that “older” ORS has the potential to ride the coat tails of “newer” zinc.¹²⁸

Further, though manufacturers recognize that rural areas are underserved and represent a potential growth opportunity for diarrhea treatments and other drugs, most are reluctant to invest resources into expanding distribution without evidence from a proven, profitable model. Consequently, some companies expressed being satisfied with the current revenues being earned from their diarrhea treatment portfolios and are not considering any significant additional investment¹²⁹.

¹²⁸ Interviews with pharmaceutical manufacturers, October 2011

¹²⁹ *Ibid*

Distribution

Key Barriers

- Distribution of ORS and zinc does not extend beyond Class I and Class II towns (>100,000 people), limiting availability of the products in rural areas, which experiences the highest burden of diarrhea
- Influencing distribution of ORS and zinc is complex due to the severely fragmented system; there are over 60,000 stockists across India

The distribution of drugs in India is a highly fragmented system, with over 60,000 super-stockists and stockists nationally¹³⁰. A large pharmaceutical company conducts business with over 2,000-5,000 independent stockists to distribute its products across the country, employing two distribution strategies that differ depending on how a drug is marketed¹³¹. The characteristics of these strategies are summarized below:

Vertically Integrated Distribution: If a manufacturer chooses to market a drug, the product is distributed through a controlled supply chain, with information technology systems to align supply with demand creation. Products are delivered to central warehouses located in the north and south of India, followed by a network of wholesalers, including C&F agents, stockists and sub-stockists who are closely affiliated with the manufacturer¹³².

Super-stockist: If a manufacturer chooses not to market a drug, the product is distributed to a super-stockist, who is an independent business owner that operates similar to a regional warehouse. Often, the super-stockist will establish relationships with a network of stockists and sub-stockists to become “authorized distributors,” availing them of incentives such as volume discounts and lines of credit. A sales force, established by the super-stockist, will manage the network of stockists and sub-stockists to remain competitive.

These distribution strategies are largely limited to Class I and Class II towns (>100,000 people), and do not formally extend to rural and micro-interior areas. Distribution in rural and micro-interior areas operate under a “demand-led” distribution system, with few products being deliberately introduced and pushed to rural areas. Often, within a block in a district of a state, 1-2 large chemists will forge relationships with stockists and operate as a mini-wholesaler for the providers (i.e. retailers, RMPs) situated within the block (~100), informally becoming the key source for drugs, credit and information. A survey in four districts in Uttar Pradesh found that 50% of retailers surveyed procured ORS from a stockist, and 27% procured ORS from a large chemist¹³³. This system threatens consistent availability of ORS and zinc in rural areas due to low demand for the products.

Rural Distribution

Approximately 742 million people reside in rural areas in India, accounting for 67% of the population. Nearly 80% of the rural population lives on income levels below US\$1.25 per day¹³⁴.

Currently, the majority of growth in the pharmaceutical industry is concentrated on urban (cities and class I towns) and peri-urban (class II to class IV) areas, which account for 33% of the India’s population. According to ORG/IMS Health, in 2010, peri-urban areas contributed to 38% of total pharmaceutical sales, totaling US\$3.4 billion, while rural markets accounted for 17%. Over the next 10 years, rural markets are predicted to

¹³⁰ Eric Langer and Abhijeet Kelkar. “Pharmaceutical Distribution in India.” BioPharm International, September 2008.

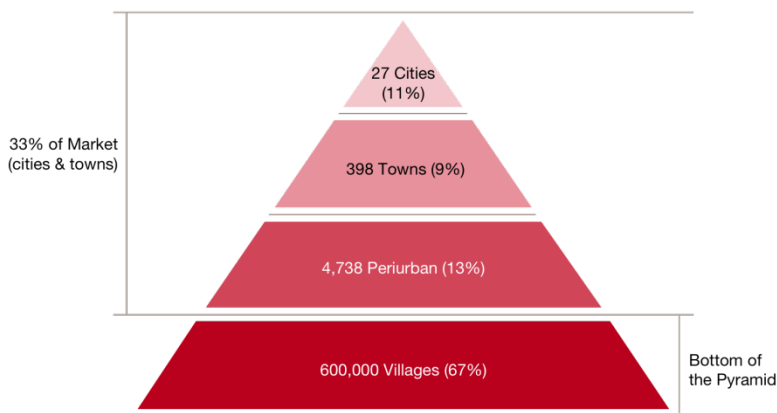
¹³¹ Anita Kotwani, and Libby Levison. “Price Components and Access to Medicines in Delhi, India.” Department for International Development (DFID), April 2007.

¹³² Interviews with pharmaceutical manufacturers, October 2011

¹³³ Rural Research Institute (SRI). “Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management.” Submitted to UNICEF, 2008.

¹³⁴ Price Waterhouse Cooper. “India Pharma Inc: Capitalising on India’s Growth Potential.” 2011

grow at a CAGR of 15-20%, depending on how and if current challenges are overcome¹³⁵. While pharmaceutical companies recognize this opportunity, only few have invested resources into building a sustainable and profitable rural markets practice outside of corporate social responsibility initiatives. This reluctance is primarily due to uncertainty of profitability as a result of key rural market barriers including poor infrastructure and the prevalence of unqualified providers, limited affordability and low caregiver awareness about various diseases and treatment options¹³⁶.



Source: Novartis, *Arogya Parivar: Health for the poor* (April 2010)

Figure 12: Administrative division structure in India

customizing the type and size of drugs to a "cell"¹³⁷, c) detailing providers and retailers and d) administering drug orders and micro-credit by setting up local sub-distributors. In June 2010, 270 cells had been established in 11 states, impacting nearly 42 million people in 28,000 villages, and the program migrated from a CSR initiative to a self-sustaining program with Novartis^{138,139}.

Diarrhea Alleviation through Zinc & ORS Therapy (DAZT): Led by FHI-360 in Uttar Pradesh and Gujarat, the DAZT program draws from the experience of the USAID Point-of-Use Water Disinfection and Zinc Treatment Project (POUZN), which took place between 2005-2009. By mapping and engaging Rural Medical Practitioners (RMPs) through frequent detailing by pharmaceutical manufacturer medical representatives and NGO field staff, the program aims to increase the uptake of ORS and zinc by changing provider prescribing behavior. Though the DAZT program is still in progress, results from the POUZN project indicate that RMP prescribing and chemist stocking of zinc increased from 0% to 79% and 70% in the project districts¹⁴⁰.

Project Shakti: Abt Associates led a public-private partnership pilot project in three districts in 2009 with pharmaceutical manufacturer, PharmaSynth, and consumer packaged goods company, Hindustan Unilever (HUL), to expand distribution of ORS. By leveraging a subset (70) of HUL's network of Shakti Entrepreneurs, who are women in rural areas that are trained to sell HUL products to the community, ORS profit and sales increased by 171% and 164%, respectively in one year in the project areas¹⁴¹.

¹³⁵ Ibid

¹³⁶ Vikas Bhadoria, Ankur Bhajanka, Kaustubh Chakroborty and Palash Mitra. "India Pharma 2020: Propelling access and acceptance, realising true potential." Mckinsey & Company, 2010

¹³⁷ Cell: 100 villages over 35 sq. kilometers with average 180,000 people

¹³⁸ Price Waterhouse Cooper. "India Pharma Inc: Capitalising on India's Growth Potential." 2011

¹³⁹ Interviews with pharmaceutical manufacturers, October 2011

¹⁴⁰ POUZN Project. February 2010. *Treating Childhood Diarrhea in India with ORT and zinc: Engaging the Pharmaceutical Industry and Private Providers*. Point-of-Use Water and Disinfection and zinc Treatment (POUZN) Project, AED, Washington, DC.

¹⁴¹ Anand Sinha. "Leveraging base of the pyramid entrepreneurs for ORS in India." USAID, 2010

Expanding distribution of ORS and zinc to the private sector in rural areas will be critical to scaling-up access across the country. Lessons from and synergies with existing models should be drawn on when establishing a national scale-up strategy in India.

Provider Behavior

Key Barriers

- Awareness of zinc as part of appropriate diarrhea management is low amongst private providers (qualified and unqualified)
- Awareness of ORS is high amongst private providers (qualified and unqualified), but prescribing ORS in practice is low
- Conventional behavioral change practices have proven to be ineffective in increasing the prescription rates of ORS and zinc. A research-driven approach for promoting and sustaining behavior change amongst providers is needed through the development and distribution of specific health messages via a variety of communication channels
- Private providers are under pressure to prescribe cost-effective treatments that are perceived to address the immediate symptoms of diarrhea to maintain a loyal patient base in a competitive environment

Healthcare availability for the average Indian villager

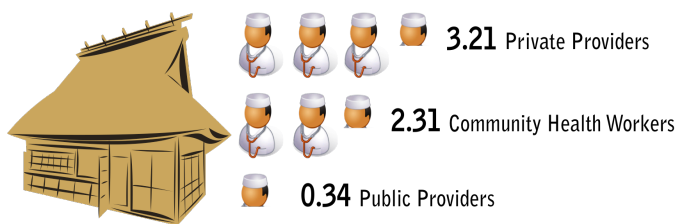


Figure 13: Average number of providers available per Indian villager *Source:* Centre for Policy Research. "Mapping Medical Providers in Rural India: Four Key Trends." February 2011.

facilities¹⁴². The government estimates, based on vacancies in sanctioned posts, that 18% of primary health centers are without a doctor, 38% are without a laboratory technician and 16% are without a pharmacist¹⁴³. Further, the quality of care in public sector clinics is reportedly atrocious; a study in New Delhi found that providers spend less than two minutes with each patient and asked on average one question before issuing a diagnosis to the patient. Researchers believe this negligence is due to limited incentives within the fixed salary pay structure to motivate high-quality care, and an overall lack of employee oversight and monitoring¹⁴⁴.

As a result, nearly 80% of outpatient visits and 60% of hospital admissions occur in the private sector, leading to high out-of-pocket health spending (71%) and the risk of being driven into poverty from unexpected health shocks (4% annually)¹⁴⁵. This trend aligns with diarrhea treatment care-seeking behavior; a 2009 study led by UNICEF found that 58% of caregivers sought treatment for diarrhea from a private provider¹⁴⁶.

The Indian government has invested significant resources into building public health infrastructure, however, shortages in human resources have led to inadequately staffed public health

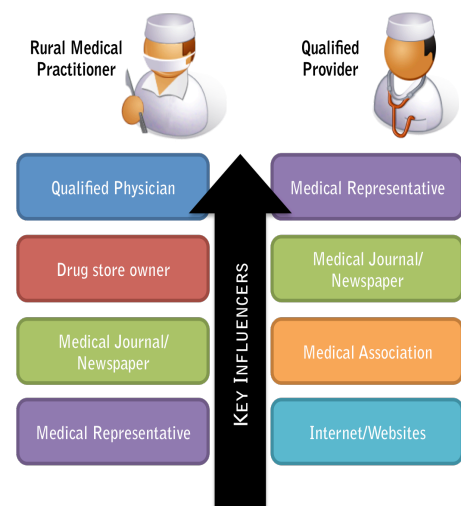


Figure 14: Key influencers for RMPs and providers *Source:* MART. "Formative research for developing communication strategy to private sector diarrhea alleviation through Zinc & ORS therapy (DAZT)." Submitted to AED Arts. 2011

¹⁴² Future Health Systems. "A Parallel Health Care Market: Rural Medical Practitioners in West Bengal, India." June 2007

¹⁴³ Mohan Rao et al. "India Towards Universal Health Coverage 5: Human resources for health in India," *Lancet*, 2011; 377: 587-598

¹⁴⁴ Jishnu Das, Jeffrey Hammer, and Kenneth Leonard. "The Quality of Medical Advice in Low-Income Countries." The World Bank Development Research Group, Jan. 2008.

In spite of the financial implications, the growth of the private health sector in India has significantly increased the availability and utilization of healthcare services in India. The average rural Indian has 6 providers available to them, of which 3.21 are private providers, 0.34 are public providers and 2.31 are community health workers (Figure 13). There is variation in these figures across the country; states with lower infant mortality rates have a lower number of providers available per village¹⁴⁷.

However, similar to the public sector, the challenge with the utilization of private health services is the quality of medical advice and care received. The reluctance of qualified private providers to practice in rural areas, due to lower pay and poor living and working conditions¹⁴⁸, has led to the emergence of a cadre of

Private Healthcare Providers in India

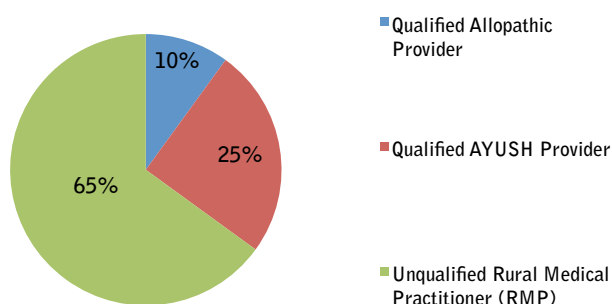


Figure 15: Overview of private providers in India *Source:* Centre for Policy Research. "Mapping Medical Providers in Rural India: Four Key Trends." February 2011

unqualified providers called Rural Medical Practitioners (RMPs). A study led by the Center for Policy Research estimates that 65% of all private providers are RMPs, which is more than double that of qualified allopathic providers (25%) and qualified AYUSH providers (10%) combined¹⁴⁹. However, although RMPs have been found to prescribe more drugs and antibiotics more frequently than qualified providers¹⁵⁰, a study conducted in New Delhi found that the quality of care provided to diarrhea patients was comparable between the cadres¹⁵¹. Hence, the poor receive inadequate care irrespective of the sector that healthcare is sought.

The following summarizes the key characteristics of each private provider.

Qualified Allopathic: Allopathic providers complete formal education and earn an MBBS degree before specializing into a specific medical field. According to the Indian Medical Council (IMC), there are approximately 640,000¹⁵² allopathic doctors practicing in different states of the country, though, they are a rarity in most rural areas¹⁵³. A consultation with an allopathic provider will typically cost between US\$1-\$2, depending on the location of the provider¹⁵⁴. Qualified provider's set-up clinics or work out of a private hospital in densely populated urban areas where they have the opportunity to charge high consultation fees¹⁵⁵. These urban areas usually benefit from uninterrupted supply of pharmaceutical products, offering these providers absolute access to all types of drugs¹⁵⁶.

¹⁴⁵ Mohan Rao et al. "India Towards Universal Health Coverage 5: Human resources for health in India," *Lancet*, 2011; 377: 587-598

¹⁴⁶ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

¹⁴⁷ Centre for Policy Research. "Mapping Medical Providers in Rural India: Four Key Trends." February 2011

¹⁴⁸ Rashmi Kumar et al. "Inequity in Health Care Delivery in India: The Problem of Rural Medical Practitioners." *Health Care Anal*, 2007; 15:223-233

¹⁴⁹ Centre for Policy Research. "Mapping Medical Providers in Rural India: Four Key Trends." February 2011

¹⁵⁰ Rashmi Kumar et al. "Inequity in Health Care Delivery in India: The Problem of Rural Medical Practitioners." *Health Care Anal*, 2007; 15:223-233

¹⁵¹ Jishnu Das, Jeffrey Hammer, and Kenneth Leonard. "The Quality of Medical Advice in Low-Income Countries." The World Bank Development Research Group, Jan. 2008.

¹⁵² World Health Organization, India Country Office. "Not enough here...too many there: health workforce in India." 2007. Available at: http://www.whoindia.org/LinkFiles/Human_Resources_Health_Workforce_in_India_-_Apr07.pdf

¹⁵³ Rashmi Kumar et al. "Inequity in Health Care Delivery in India: The Problem of Rural Medical Practitioners." *Health Care Anal*, 2007; 15:223-233. *Note:* The study finds that in Uttar Pradesh, only 5.6% of the total sample had a formal MBBS degree

¹⁵⁴ Interviews with Private Providers in Uttar Pradesh and Gujarat, November 2011

¹⁵⁵ WHO India. "Not Enough Here-Too Many There- Health Workforce in India." Web. Accessed on: November 10, 2011. Available at: http://www.whoindia.org/LinkFiles/Human_Resources_Health_Workforce_in_India_-_Apr07.pdf

¹⁵⁶ Eric Langer and Abhijeet Kelkar. "Pharmaceutical Distribution in India." *BioPharm International*, September 2008

Qualified AYUSH: AYUSH providers complete formal education programs targeted specifically to a type of recognized alternative medicine. This includes: Ayurveda, Yoga, Unani, Siddha, and Homeopathy. An estimated 3,371 hospitals and 22,014 public health clinics provide only AYUSH services¹⁵⁷. While 754,985 AYUSH doctors are registered with the Department of AYUSH at the GOI, only 200,000 are believed to be actively practicing¹⁵⁸. AYUSH providers usually operate in semi-urban or rural areas and charge a modest consultation fee. These providers are not fully dependent on the pharmaceutical distribution system, since many AYUSH medicines are homemade from medicinal plant materials.

Unqualified RMP: RMPs have no formal medical education and largely practice allopathic medicine on the basis of work experience under a qualified provider¹⁵⁹. In most rural areas in India, RMPs are the first point of contact for treatment, especially for acute diseases. This behavior is driven by factors including proximity, availability, affordability and perks such as credit for medication¹⁶⁰. RMPs operate as small-business owners, building loyal customer bases by offering 24/7 care, empathy and compliance with caregiver requests. Typically, RMPs charge caregivers USD\$0.20 for the cost of a consultation¹⁶¹. Some RMPs also dispense drugs. In the case of diarrhea treatment, a study in four districts in UP found that RMPs charged an average USD\$1.15 for a consultation and treatment (ORS and zinc)¹⁶². Largely detached from traditional sources of health information such as MRs and CMEs, RMPs have strong professional linkages with qualified private allopathic providers. This is structured as either a formal arrangement, such as a mentor-mentee relationship or an incentivized referral agreement, or informally, by following a qualified private allopathic provider's prescriptions. The latter is achieved by studying the prescriptions brought by caregivers to consultations, presumably as a substitute for a medical record¹⁶³. This illustrates the cascading impact that an influential qualified provider has on the uptake of certain health products across the hierarchy of health workers¹⁶⁴. Linkages also exist between RMPs and retailers to ensure drugs prescribed are actually available for purchase.

Though the total number of RMPs across India is unknown, one district in Andhra Pradesh was found to have an estimated 3,030 RMPs¹⁶⁵, and the USAID/AED Point-of-Use Water Disinfection and Zinc Treatment (POUZN) project identified 20,000 RMPs in 10 districts in Uttar Pradesh¹⁶⁶. Addressing this proliferation of RMPs has largely been neglected at the policy level. Though a task force under NRHM was established in 2006 to examine the accreditation, training and integration of RMPs into the formal health system, recommendations made in 2007 by the group have since remained idle¹⁶⁷. In certain states, the Supreme Court of India has filed public interest litigation against RMPs, however, a lack of capacity in the system has led to a dearth of open files¹⁶⁸. These setbacks, however, are not without some validity, as the issue of RMPs is a contentious one, since a complete ban of the cadre would severely erode access to healthcare in rural areas. Recently, the GOI announced that it was considering establishing a new cadre of non-physician clinicians that are trained in a designation called "Bachelors of Rural Health", but pushback from the medical fraternity and equity issues have since halted such efforts.

ASHAs: The GOI is aware of the shortages in the availability of qualified providers, and the additional capacity required to improve health outcomes. As a result, since the launch of the National Rural Health Mission

¹⁵⁷ Department of AYUSH, Government of India. Web. Accessed on November 10, 2011. Available at: www.indianmedicine.nic.in

¹⁵⁸ Mohan Rao et al. "India Towards Universal Health Coverage 5: Human resources for health in India," *Lancet*, 2011; 377: 587-598

¹⁵⁹ Rashmi Kumar et al. "Inequity in Health Care Delivery in India: The Problem of Rural Medical Practitioners." *Health Care Anal*, 2007; 15:223-233. *Note:* The study finds that in Uttar Pradesh, only 5.6% of the total sample had a formal MBBS degree

¹⁶⁰ *Ibid*

¹⁶¹ Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008

¹⁶² *Ibid*

¹⁶³ Interviews with non-profit organizations, September 2011

¹⁶⁴ Formative Research For Developing Communication Strategy To Private Sector

¹⁶⁵ K.V. Narayana. "The unqualified medical practitioners: methods of practice and nexus with the qualified doctors." *Centre for Economic and Social Studies*, May 2006

¹⁶⁶ POUZN Project. February 2010. *Treating Childhood Diarrhea in India with ORT and zinc: Engaging the Pharmaceutical Industry and Private Providers*. Point-of-Use Water and Disinfection and zinc Treatment (POUZN) Project, AED, Washington, DC.

¹⁶⁷ National Rural Health Mission, Ministry of Health and Family Welfare, Government of India. "Task-Group set up to examine Accreditation, Training and Integration of Private Rural Medical Practitioners." April 2007.

¹⁶⁸ David H. Peters and V.R. Muraliedharan. "Regulating India's Health Services: To what end? What future?" *Social Science and Medicine*, 2008; 66: 2133-2144

(NRHM) in 2005, the availability of female community health workers in the public health sector, called “Accredited Social Health Activists (ASHAs),” has been prioritized. India now has 700,000 ASHA workers, who receive incentivized compensation for managing specific health services for blocks of 1,000 people¹⁶⁹, and supplement healthcare sought in the private sector.

Diarrhea Treatment Prescribing Behavior

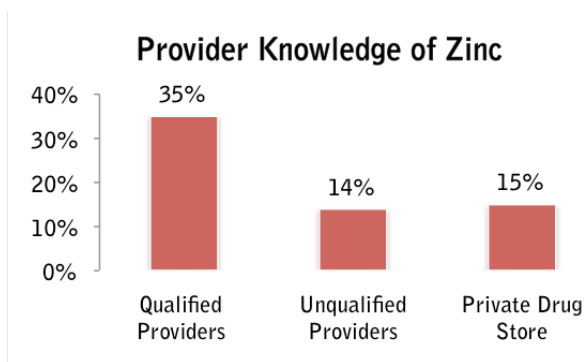


Figure 16: Provider knowledge of zinc *Source:* UNICEF. “Management Practices for Childhood Diarrhea in India.” 2009

There is a discrepancy between what providers know they should do to treat diarrhea and what they actually do, often referred to as the “know-do” gap. A study led by UNICEF in one district in 10 states found that almost 90% of private providers claimed to prescribe ORS, and 46% stocked the product¹⁷⁰. Another study in four districts in Uttar Pradesh found that providers perceived ORS favorably, agreeing with statements including: first line of treatment for diarrhea (89%), available (94%), affordable (94%) and appropriate for any child with diarrhea (88%). Despite these claims, the prescription of ORS reported by caregivers is low, ranging from 19% in a study in 15 districts in Bihar¹⁷¹ to 47% in the UNICEF study across 10 states¹⁷².

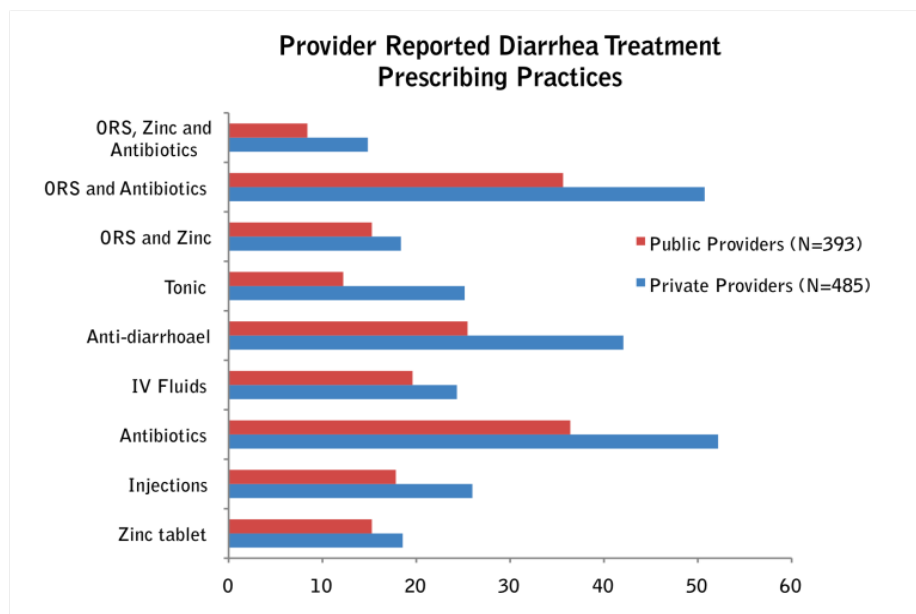


Figure 17: Provider diarrhea treatment prescribing practices *Source:* UNICEF. “Management Practices for Childhood Diarrhea in India.” 2009

¹⁶⁹ Rashmi Kumar et al. “Inequity in Health Care Delivery in India: The Problem of Rural Medical Practitioners.” *Health Care Anal*, 2007; 15:223-233. *Note:* The study finds that in Uttar Pradesh, only 5.6% of the total sample had a formal MBBS degree

¹⁷⁰ UNICEF. “Management Practices for Childhood Diarrhea in India.” 2009

¹⁷¹ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. “Reducing deaths from Diarrhea in the Indian State of Bihar.” Funded by Children’s Investment Fund Foundation, 2011

¹⁷² UNICEF. “Management Practices for Childhood Diarrhea in India.” 2009

This know-do gap is found to extend to zinc, though perceptions of the product are less favorable. In the 10 states included in the UNICEF study, nearly 19% of private providers reported prescribing zinc for diarrhea, but only 1.3% of caregivers reported being prescribed zinc¹⁷³. In four districts in Uttar Pradesh, a limited number of the providers surveyed (n=300) believed that zinc was the first line treatment for diarrhea (9%), available (17%), and appropriate for any child with diarrhea (16%)¹⁷⁴. Further, RMPs interviewed in Uttar Pradesh and Gujarat did not believe that zinc was an efficacious, immediate relieving treatment for diarrhea, and perceived it to be more expensive than antibiotics¹⁷⁵.

The implication of these findings is two fold: firstly, the gap between knowledge and practice provides sufficient evidence that training and educating providers alone is not going to significantly move the needle on the uptake of ORS and zinc. Secondly, communicating the benefits and clinical evidence of zinc requires a more thoughtful and compelling communication strategy. Lessons from the USAID POUZN project describe the need for key opinion leaders to endorse zinc in addition to engaging face-to-face with providers repeatedly to change prescribing behavior¹⁷⁶. Those providers who were found to be aware of ORS and zinc in four districts in Uttar Pradesh reported learning about the products from mass media (64%), community health workers (ANM, ANW, ASHA; 26%), friends/relatives (22%), government programs (18%) and posters (14%)¹⁷⁷.

Until these strategies are implemented, combinations of alternative medications including antibiotics, anti-diarrheals, IV fluids and injections will continue to be prescribed as the primary treatment for diarrhea. Various studies have confirmed this prescribing behavior, though significant variation exists between the types of treatments prescribed and whether it is caregiver or provider reported (Table 5).

¹⁷³ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

¹⁷⁴ Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008

¹⁷⁵ MART. "Formative research for developing communication strategy to private sector diarrhea alleviation through Zinc & ORS therapy (DAZT)." Submitted to AED Arts. 2011

¹⁷⁶ POUZN Project. February 2010. *Treating Childhood Diarrhea in India with ORT and zinc: Engaging the Pharmaceutical Industry and Private Providers*. Point-of-Use Water and Disinfection and zinc Treatment (POUZN) Project, AED, Washington, DC.

¹⁷⁷ Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008

	UNICEF Study ¹ 10 states; 1 district Caregivers reported N=9,298 % of mothers who used treatment(s) x to treat their child's diarrhea episode of all mothers surveyed that sought outside treatment for their child's diarrhea episode in the last two weeks	Baseline Survey ² Bihar; 15 districts Caregiver reported N=437 % of mothers who used treatment(s) x to treat their child's diarrhea episode of all mothers surveyed that had a child with diarrhea in the in last two weeks	UNICEF Study ³ 10 states; 1 district Provider reported N=485 % of private providers that reported prescribing treatment(s) x of all private providers surveyed (includes private allopathic, unqualified health practitioner, AYUSH private, and private chemists)	UNICEF Study ⁴ Uttar Pradesh; 4 districts Provider reported N=192 % of providers and retailers that used treatment x for the last diarrhea episode treated of all providers and retailers surveyed (from the public and private sector)
Antibiotics	5.6	12.8	52	66
Anti-diarrheal	18.2	11.9	42	17
IV Fluids	1.1	0.69	24	2
Injections	23	19	26	31.8
Tonics	31.5	N/A	25	N/A
ORS	47	19.7	89	85
Zinc	1.3	3	18.6	23.4*
Others	N/A	64.3	N/A	49.5**

Table 5: Overview of treatments prescribed for diarrhea as reported by caregivers and providers in various studies. ¹UNICEF. "Management Practices for Childhood Diarrhea in India," 2009; ² Dr. Christa L. Fischer Walker, and Dr. Sunita Taneja. "Reducing deaths from Diarrhea in the Indian State of Bihar." Funded by Children's Investment Fund Foundation, 2011; ³ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009; ⁴Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2009

*Includes Zinc and Zinc with Multivitamin

**Includes homemade fluids and AYUSH pills and syrups

This behavior and variation is influenced by a number of factors, which are summarized below in no particular order:

Hawthorne effect: Providers surveyed are subject to the "Hawthorne effect¹⁷⁸," which is described as modified behavior in response to the fact that one is being studied. This phenomenon may partly explain the discrepancy between what providers report that they do or know that they should do and what they actually do in regards to diarrhea treatment.

Caregiver expectations: Provider recommendations are strongly influenced by caregiver expectations, which include immediate relief treatment, and a high number of drugs for a low price. Antibiotics, anti-diarrheals, injections and others are considered to fulfill this expectation in comparison to ORS, which is sometimes perceived as a cheap and ineffective treatment¹⁷⁹. Private providers face added pressure to respond to caregiver demands to sustain business operations and a loyal customer base. In fact, RMPs in

¹⁷⁸ Jishnu Das, Jeffrey Hammer, and Kenneth Leonard. "The Quality of Medical Advice in Low-Income Countries." The World Bank Development Research Group, Jan. 2008.

¹⁷⁹ MART. "Formative research for developing communication strategy to private sector diarrhea alleviation through Zinc & ORS therapy (DAZT)." Submitted to AED Arts. 2011

Uttar Pradesh and Gujarat reported that caregivers threatened to consult other providers if antibiotics were not prescribed¹⁸⁰.

Provider knowledge and belief: As previously mentioned, awareness and belief in the appropriate diarrhea treatment (ORS and zinc) is low amongst providers, especially those in the private sector. RMPs interviewed in Uttar Pradesh and Gujarat reported that since caregivers often sought diarrhea treatment at stage 2 or 3 of the episode, they felt obliged to prescribe antibiotics or an anti-diarrheal¹⁸¹; these treatments are considered to be highly efficacious for diarrhea treatment since they provide quick relief.

Market dynamics: The perception of a treatment's availability, cost and profitability is factored into a provider's prescribing decision. For instance, providers may advise caregivers to make sugar-salt-solution at home, and only purchase antibiotics or an antidiarrheal to save money¹⁸². Liaising with retailers is also common to ensure that providers prescribe drugs that are actually available¹⁸³.

¹⁸⁰ Ibid

¹⁸¹ MART. "Formative research for developing communication strategy to private sector diarrhea alleviation through Zinc & ORS therapy (DAZT)." Submitted to AED Arts. 2011

¹⁸² Ibid

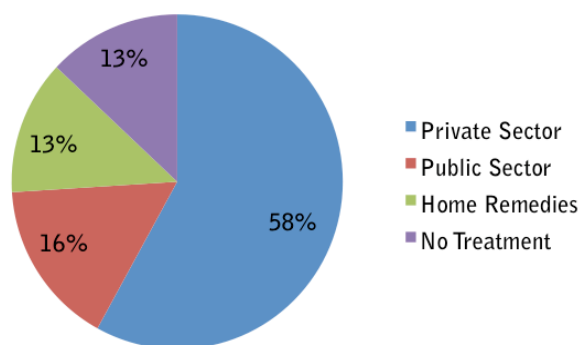
¹⁸³ Interviews with non-profit organizations, September 2011

Caregiver Behavior

Key Barriers

- Caregivers do not perceive diarrhea as a life-threatening disease. Approximately 25% of caregivers do not seek treatment for diarrhea or rely on home remedies¹⁸⁴
- Caregivers prefer antibiotics, anti-diarrheals and tonics for diarrhea treatment because a) they are perceived to provide quick and immediate relief, b) the number of drugs are often equated with the relative efficacy of the treatment c) they are easily available and more affordable than ORS and zinc combined
- ORS is not considered to be an effective diarrhea treatment by caregivers. Though 70% of caregivers were found to be aware of ORS, only 35% used it for diarrhea treatment¹⁸⁵
- Awareness of zinc as the recommended treatment for diarrhea amongst caregivers is nil¹⁸⁶

Treatment Seeking Behavior for Diarrhea



Antibiotics, anti-diarrheals, injections and tonics are the most common treatments used for diarrhea in India. Between 70-90% of caregivers surveyed in select districts in Uttar Pradesh¹⁸⁷, Bihar¹⁸⁸ and Gujarat¹⁸⁹ reported using at least one of these products to treat childhood diarrhea. This pales in comparison to ORS and zinc, which together is used by less than 1% of caregivers¹⁹⁰. Studies have shown that 58% of caregivers seek treatment from the private sector, which is approximately 3.5 times more than the public sector (16%)¹⁹¹. Nearly 26% of caregivers treat childhood diarrhea with home remedies or nothing at all¹⁹².

Figure 18: Caregiver diarrhea treatment health source *Source:* UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

Diarrhea Treatment Knowledge, Attitudes and Perceptions

There are a number of reasons that account for poor caregiver uptake of ORS and zinc in India. First, caregivers do not perceive diarrhea to be a life-threatening disease, and generally take a "wait and watch" attitude towards seeking treatment. As a result, caregivers seek treatment for diarrhea 1-2 days after the onset of symptoms or when the symptoms appear severe¹⁹³. A survey led by international NGOs in Uttar

¹⁸⁴ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

¹⁸⁵ Ibid

¹⁸⁶ Ibid

¹⁸⁷ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Enhancing the Uptake of ORS and Zinc in Targeted Areas of India: Baseline cross sectional survey internal report." Funded by Children's Investment Fund Foundation, 2011

¹⁸⁸ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Reducing deaths from Diarrhea in the Indian State of Bihar." Funded by Children's Investment Fund Foundation, 2011

¹⁸⁹ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Enhancing the Uptake of ORS and Zinc in Targeted Areas of India: Baseline cross sectional survey internal report." Funded by Children's Investment Fund Foundation, 2011

¹⁹⁰ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

¹⁹¹ Ibid

¹⁹² Ibid

¹⁹³ MART. "Formative research for developing communication strategy to private sector diarrhea alleviation through Zinc & ORS therapy (DAZT)." Submitted to AED Arts. 2011

Pradesh and Gujarat found that over 70% of caregivers only seek treatment for diarrhea if the child develops fever or vomits constantly¹⁹⁴.

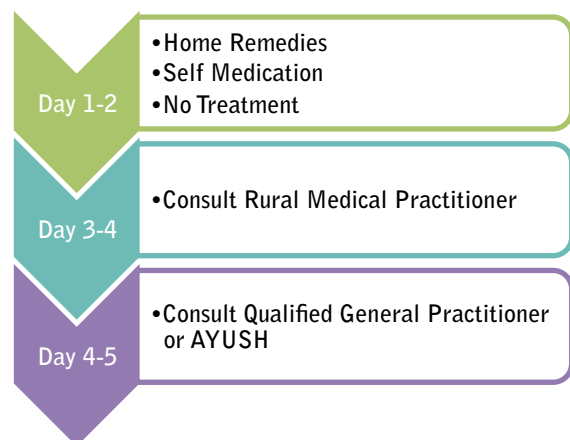


Figure 19: Overview of caregiver diarrhea treatment seeking behavior *Source:* MART. "Formative research for developing communication strategy to private sector diarrhea alleviation through Zinc & ORS therapy (DAZT)." Submitted to AED Arts, 2011

According to a report released by a market research firm on diarrhea treatment practices in Uttar Pradesh and Gujarat, caregivers will typically treat children with home remedies on day 1 and day 2 of a diarrhea episode, since the disease is considered to be short and easily curable. These home remedies, which are usually passed on to caregivers by mothers, mother in laws, grandmothers and neighbors, include sugar-salt-lemon or sugar-salt solution and other state-specific mixtures. For instance, in UP, fennel seeds boiled in water, onion juice and a roasted mixture of asfoetida, carom seed, and myrobalans (e.g. amla fruit) are given to children during the first two days of the diarrhea episode, whereas, in Gujarat, the usage of commercially packaged ORS as a home remedy is high. By day 3, if the frequency of stools has not subsided, caregivers will seek treatment from an RMP. In instances where the diarrhea symptoms persist until day 5 and day 6, a qualified provider will be consulted¹⁹⁵. When outside treatment is sought by a caregiver, provider (unqualified or qualified) recommendations are often influenced by his

or his perception of caregiver expectations. However, caregivers report that they heed to provider recommendations. This communication gap contributes to a perpetuating cycle of incorrect perceptions and prescriptions for diarrhea treatment. In some cases, however, caregivers demand antibiotics or anti-diarrheals from providers, threatening to otherwise seek treatment elsewhere¹⁹⁶.

Second, caregivers do not value the benefits of ORS for diarrhea treatment, in comparison to antibiotics, injections, anti-diarrheals and tonics, which are perceived to offer "immediate relief treatment." One study found that caregivers perceived ORS to be equivalent to home remedies or *glucose* and not a medicine¹⁹⁷; this may be the result of years of government-led social marketing which promoted the use of "home solutions or ORS" for diarrhea treatment. As a result, a gap between ORS knowledge (70%) and usage (38%) amongst caregivers remains. However, although caregiver knowledge of ORS is high, studies in Uttar Pradesh, Gujarat and Bihar found that caregivers lack an understanding of the link between ORS and rehydration, reporting that the drug should be used for diarrhea and vomiting^{198,199}. In some cases, this knowledge gap extends to ORS preparation; a study in Kashmir found that only approximately 18% of mothers knew how to correctly prepare ORS²⁰⁰.

Third, awareness of zinc amongst caregivers is low. Studies have shown that only between 1²⁰¹-10%²⁰² of caregivers are aware of the use of zinc for diarrhea treatment. Other caregivers believed zinc was used as a

¹⁹⁴ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Enhancing the Uptake of ORS and Zinc in Targeted Areas of India: Baseline cross sectional survey internal report." Funded by Children's Investment Fund Foundation, 2011

¹⁹⁵ MART. "Formative research for developing communication strategy to private sector diarrhea alleviation through Zinc & ORS therapy (DAZT)." Submitted to AED Arts, 2011

¹⁹⁶ Interviews with non-profit organizations, September 2011

¹⁹⁷ MART. "Formative research for developing communication strategy to private sector diarrhea alleviation through Zinc & ORS therapy (DAZT)." Submitted to AED Arts, 2011

¹⁹⁸ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Enhancing the Uptake of ORS and Zinc in Targeted Areas of India: Baseline cross sectional survey internal report." Funded by Children's Investment Fund Foundation, 2011

¹⁹⁹ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Reducing deaths from Diarrhea in the Indian State of Bihar." Funded by Children's Investment Fund Foundation, 2011

²⁰⁰ Renata Seidel. "Behavior Change Perspectives and Communication Guidelines on Six Child Survival Interventions: Chapter 4 - Diarrheal Diseases." Joint publication of the John Hopkins School of Public Health, Center for Communication Programs, and AED with support from UNICEF. December 2005

²⁰¹ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

fertilizer (52%), tonic (5%) or for a cough (3%). In Bihar, 75% of caregivers that had heard of zinc reported learning about the drug from mass media and private providers²⁰³, whereas in Uttar Pradesh and Gujarat, private providers and private hospitals were the more common information source (87%)²⁰⁴. In contrast, only between 5-23% of caregivers in all three states learned about zinc through a public provider (i.e. PHC, ANM, AWW, AWC, ASHA).

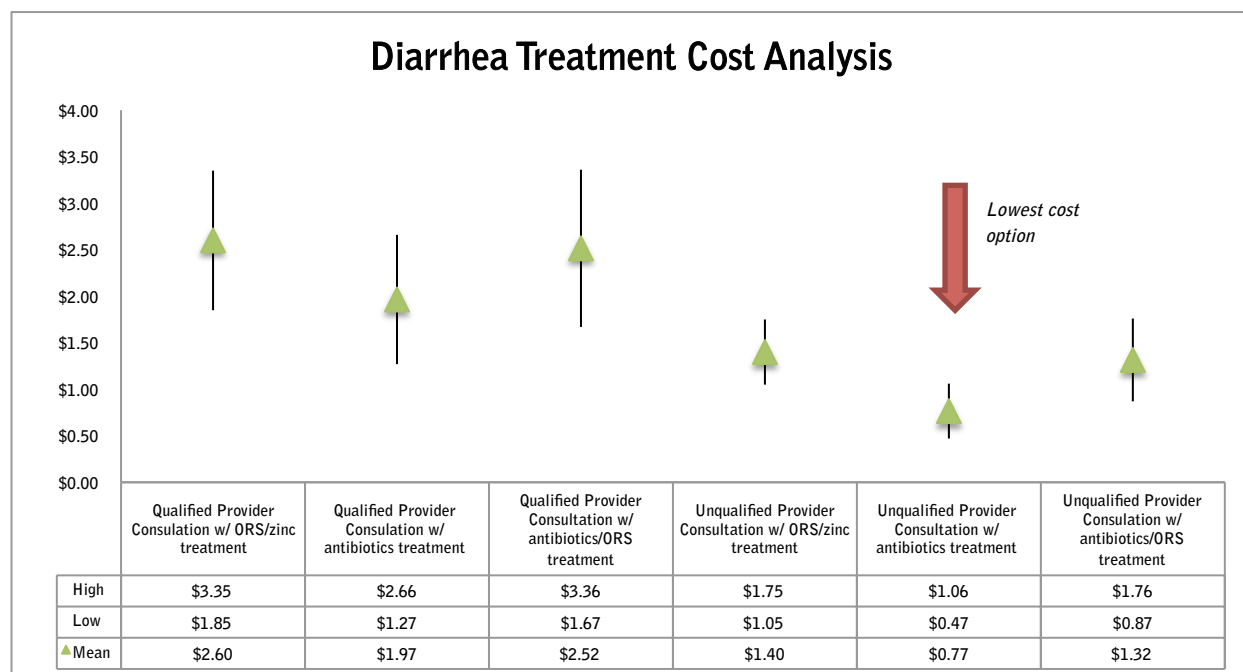


Figure 20: Diarrhea treatment cost analysis Sources: 1) Retail price of two 20g ORS sachets US\$0.20-\$0.35; AED. "ORS Producers Matrix." Updated September 16, 2011 2) Retail price of 10 tablets of 20mg Zinc Sulfate US\$0.45 – \$0.65; AED. "Zinc Producers Matrix." Updated September 16, 2011 3) Retail price of three tablets of antibiotic, Ofloxacin-Ornidazole, US\$0.27-\$0.66; <http://www.mims.com/India> 4) Cost of consultation with qualified provider US\$1.00 - \$2.00; Cost of consultation with unqualified provider US\$0.20 - \$0.40; Interviews with Private Providers in Uttar Pradesh, Gujarat, New Delhi, November 2011

Lastly, the affordability of ORS and zinc may impact caregiver uptake of the products; the mean cost of treatment with a consultation can vary between US\$1.40 and \$2.60 (Figure 20). In comparison, the mean cost of treating diarrhea with a three-day course of Ofloxacin-Ornidazole ranges from US\$0.77 to \$1.97. This analysis illustrates the opportunity to reduce the overall cost of a treatment course of ORS and zinc through various supply strategies to achieve a more competitive and affordable price point for caregivers.

²⁰² Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Reducing deaths from Diarrhea in the Indian State of Bihar." Funded by Children's Investment Fund Foundation, 2011

²⁰³ Ibid

²⁰⁴ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Enhancing the Uptake of ORS and Zinc in Targeted Areas of India: Baseline cross sectional survey internal report." Funded by Children's Investment Fund Foundation, 2011

Retailer Behavior

Key Barriers

- Low awareness and knowledge of the correct treatment for diarrhea amongst retailers
- Misaligned incentives for retailers to stock and promote ORS and zinc in comparison to alternative treatments
- Overlap between providers and retailers in terms of prescribing and dispensing diarrhea treatment
- Sale of prescription drugs, without a prescription, to foster consumer patronage

There are approximately 550,000 pharmacies in India, of which approximately 75% of them operate independent community, hospital and government practices²⁰⁵. Although the WHO has recognized the role of

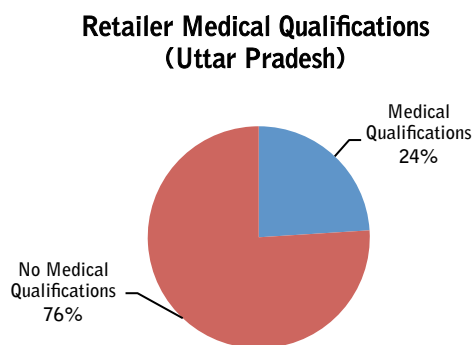


Figure 21: Overview of retailer medical qualifications *Source:* Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008

pharmacists as a key provider of primary healthcare, health and pharmaceutical reform policies in India have historically not included them due to the lack of clarity about a pharmacist's role beyond the supply and distribution of drugs²⁰⁶. Though pharmacists are required to complete a diploma in pharmacy (D. Pharm), which is a 2-year program after high school and includes 3 months of practical training in a hospital pharmacy, to apply for a pharmacy license, this regulation is not actively enforced²⁰⁷. As a result, the majority of pharmacies in India are not operated by a qualified pharmacist, especially in rural areas. A study led by UNICEF in Uttar Pradesh found that 76% of pharmacists interviewed (n=223) did not have any medical qualifications and about 22% of the sample did not have any practical training. However, the same study found that

nearly 80% of pharmacists reported obtaining training from alternative sources as opposed to formal education, including from practicing physicians (35%), by training as a compounder (22%) or completing the training course for ANWs (11%)²⁰⁸. Research conducted in Mumbai found that while most pharmacy owners had the appropriate medical qualification they did not manage day-to-day operations of the pharmacy. About 99% of caregivers surveyed were assisted by a clerk, of which only 41% had the appropriate medical qualifications to operate the pharmacy²⁰⁹.

The spread of pharmacies in India is skewed to urban areas, since pharmacists are reluctant to work in rural areas, citing low profits and unreliable drug distribution as barriers to business sustainability²¹⁰. However, in both geographies, the pharmacist plays a critical role in the diagnosis and treatment of diseases, often blurring the lines between the role of providers and retailers. A study conducted by UNICEF in Uttar Pradesh defined qualified retailers as anyone that dispensed drugs, which included pharmacists, in addition to

²⁰⁵ South East Asian FIP-WHO Forum of Pharmaceutical Associations in collaboration with WHO-India Country Office. "Challenges and Opportunities for Pharmacists in Health Care in India." November 2007

²⁰⁶ Ibid

²⁰⁷ Ibid

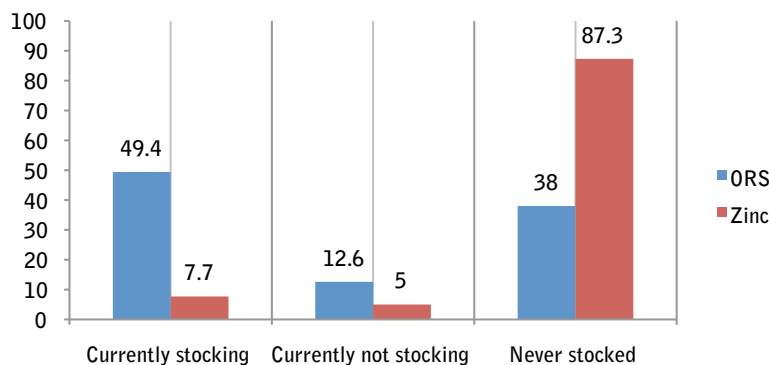
²⁰⁸ Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008

²⁰⁹ Kamat VR and Nichter M. "Pharmacies, self-medication and pharmaceutical marketing in Bombay, India," *Soc Sci Med* 1998; 47(6): 779-794

²¹⁰ South East Asian FIP-WHO Forum of Pharmaceutical Associations in collaboration with WHO-India Country Office. "Challenges and Opportunities for Pharmacists in Health Care in India." November 2007

qualified private providers, RMPs, ANMs and ANWs amongst others²¹¹. In another small study in two villages of one district in Uttar Pradesh, researchers found that 43% of caregivers directly consulted a pharmacist for health advice²¹²; similarly, in 15 districts in Bihar, 17% of caregivers perceived pharmacists to be an appropriate source of care for diarrhea²¹³. However, it can be assumed that this behavior varies from state to state depending on the distribution of pharmacists, RMPs, qualified providers etc.; an alternative study in select districts in Gujarat and Uttar Pradesh on caregiver diarrhea treatment seeking behavior, did not cite pharmacists as an appropriate source of care²¹⁴.

Retailer Diarrhea Treatment Stocking Patterns



The combination of minimal education with the provision of drug prescription and dispensing has contributed to the inappropriate treatment of diarrhea at the retail level. Similar to providers, a “know-do” gap exists. UNICEF’s study across one district in 10 states found that nearly 88% of retailers reported recommending ORS and 11% reported recommending zinc for diarrhea treatment, while only 47% and less than 2% of caregivers in the same study reported receiving ORS and zinc.

Figure 22: Retailer diarrhea treatment stocking patterns *Source: Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008*

In contrast, approximately 40% of retailers believed that antibiotics were the appropriate treatment for diarrhea²¹⁵. A study in Uttar Pradesh found that retailers prescribed ORS (85%), antibiotics (78%) and injection antibiotics (28%) most often to the most recent diarrhea patients²¹⁶.

Interviews with retailers in New Delhi and Lucknow, Uttar Pradesh revealed that retailer stocking decisions are primarily driven by perceived consumer demand, though profit potential and confirmation of provider prescribing can also influence stocking decisions²¹⁷. According to the survey conducted by market research firm, IMRB, in Uttar Pradesh, 50% of retailers have either never stocked ORS or did not have any in stock during the survey period; 88% of the same retailers surveyed reported to have never stocked zinc. Low consumer demand and awareness of ORS were the primary reasons for not stocking ORS; 15% of retailers reported being dissatisfied with the low profit margin of the product. Retailers seldom stocked zinc due to limited awareness of the product. However, the study also found that about 74% of retailers were prepared to stock ORS and about 70% retailers were prepared to stock zinc if the products were supplied to them at their shop and other supply chain bottlenecks were addressed. Of those retailers that did stock ORS, majority procured the product from wholesalers (50%), large pharmacies (27%), salesmen (7%) or distributors (3%) either once or twice a month (80%)²¹⁸.

²¹¹ Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008

²¹² Ibid

²¹³ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Reducing deaths from Diarrhea in the Indian State of Bihar." Funded by Children's Investment Fund Foundation, 2011

²¹⁴ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Enhancing the Uptake of ORS and Zinc in Targeted Areas of India: Baseline cross sectional survey internal report." Funded by Children's Investment Fund Foundation, 2011

²¹⁵ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

²¹⁶ Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008

²¹⁷ Interviews with retailers, October 2011

²¹⁸ Rural Research Institute (SRI). "Market Survey on Market Availability and Uptake of ORS and Zinc for Diarrhoea Management." 2008

Though profit margins are not the primary driver for retailer stocking and prescribing decisions, they do play a role in the decision-making algorithm, since pharmacies operate in extremely competitive environments. Most pharmacies are located in close proximity to each other, cluttered especially near hospitals and provider clinics. In some cases, this intensified competition influences unethical business practices, including the sale of prescription drugs without prescriptions (including antibiotics and anti-diarrheals for diarrhea treatment), undercutting competitors, offering discounts, selling expired goods and company samples and recommending unnecessary drugs²¹⁹. A study conducted by the University of Arizona and Emory University on drug dispensing behavior of pharmacists in India found that 66% of all drugs purchased were without a prescription, of which 27% were antibiotics. The study also highlighted that more than 50% of prescription only anti-diarrheals were purchased without a prescription directly from a pharmacy²²⁰.

²¹⁹ South East Asian FIP-WHO Forum of Pharmaceutical Associations in collaboration with WHO-India Country Office. "Challenges and Opportunities for Pharmacists in Health Care in India." November 2007

²²⁰ Kamat VR and Nichter M. "Pharmacies, self-medication and pharmaceutical marketing in Bombay, India," Soc Sci Med 1998; 47(6): 779-794

Supply side barriers to ORS/zinc uptake

Limited investment in marketing of ORS and zinc

Few pharmaceutical manufacturers invest adequate resources to commercially market ORS and zinc, which are both low-volume, low-margin products. In many cases, ORS and zinc are not considered a priority within a large manufacturer's product portfolio, which is increasingly focused on drugs for lifestyle diseases. As a result, perceptions of ORS as an effective treatment for diarrhea are weak, and awareness of zinc is low. Those manufacturers that do invest resources into marketing ORS and zinc during the diarrhea season often reduce profit margins to compensate for the high mass media costs. In the case of zinc, marketing is limited to providers, since the current drug status of the product restricts direct to consumer marketing. Manufacturers interviewed believed that executing a large-scale national awareness campaign sponsored by the GOI and changing zinc's regulatory status to OTC could impact the uptake of the products.

Irregular supply of ORS/zinc to rural areas

Drug distribution is limited to Class I and Class II towns (>100,000 people), since they offer a market that will clearly provide a return on investment. Beyond this point, drug distribution is demand led, and conducted through informal relationships forged between large retailers in a block or district with stockists or sub-stockists who can offer products on credit. Large retailers then subsequently supply product to other retailers in the block or district. As a result, consistent availability of low demand products such as ORS and zinc in comparison to high demand products such as antibiotics and anti-diarrheals is low in rural areas. Though pharmaceutical manufacturers recognize the opportunity of rural markets, those interviewed were generally reluctant to invest the initial capital required to expand distribution. In some cases, manufacturers have partnered with non-profit organizations and/or fast-moving consumer product good (FMCG) companies that reach rural areas to distribute public health products, including ORS and zinc.

Demand side barriers to ORS/zinc uptake

Caregivers prefer alternative treatments to ORS/zinc for diarrhea

Caregivers do not perceive ORS to be an effective treatment for diarrhea in comparison to antibiotics, anti-diarrheals and tonics. Though awareness of ORS is high (55%-88%), usage is low (15-38%)^{221,222,223}. This "know-do" gap is driven by four key factors. First, ORS is not believed to provide "immediate relief" from diarrhea symptoms in comparison to alternative treatments – an outcome that is highly valued for poor families with demanding work lifestyles. Second, ORS is considered synonymous with home remedies such as sugar and salt solution, reducing the willingness to pay for the product. Third, the purpose of ORS and concept of rehydration is misunderstood. Lastly, latent demand for ORS is lost since providers report basing prescribing decisions on perceptions of caregiver preferences, while caregivers report heeding to provider recommendations. Zinc, on the other hand, suffers from low awareness amongst caregivers and RMPs and low confidence in the efficacy of the product amongst qualified providers. Due to limited marketing and promotion of zinc, the introduction of the new product for diarrhea treatment has not been able to shift current market dynamics from antibiotics, anti-diarrheals and tonics. Repositioning ORS and zinc through the introduction of a co-package product and a high-impact branding campaign, with the support of public and

²²¹ Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Reducing deaths from Diarrhea in the Indian State of Bihar." Funded by Children's Investment Fund Foundation, 2011

²²² Dr. Christa L. Fischer Walker and Dr. Sunita Taneja. "Enhancing the Uptake of ORS and Zinc in Targeted Areas of India: Baseline cross sectional survey internal report." Funded by Children's Investment Fund Foundation, 2011

²²³ UNICEF. "Management Practices for Childhood Diarrhea in India." 2009

private stakeholders, including the GOI, may help shift provider and caregiver perceptions of the products and subsequently increase uptake.

Caregivers do not perceive diarrhea to be life threatening

Caregivers do not consider diarrhea to be life threatening, rather believing that the disease is a “fact of life” that can be managed at home. Approximately 26% of all caregivers do not seek outside treatment for diarrhea, of which 50% do not administer any treatment at all²²⁴. In general, caregivers take a casual “wait and watch” attitude to diarrhea, offering home remedies on day 1-2 and only visiting a provider on day 3 if symptoms do not subside. In part due to this delayed treatment seeking behavior, providers feel pressured to prescribe alternative treatments including antibiotics, anti-diarrheals and tonics to address the immediate symptoms of diarrhea and “stop the stools”, or risk losing a consumer to another provider.

Conclusion

This assessment provides an overview of the current market dynamics governing the diarrhea treatment market in India and offers insights into the factors hindering wide-scale uptake of ORS and zinc in the country. On the supply side, the perception of ORS and zinc as low-volume, low margin products combined with internal competing priorities has limited investment in the marketing and expanded distribution of these products. On the demand side, poor perception and value for the comparative benefits of ORS and low awareness of zinc, has led to a preference for alternative diarrhea treatments such as antibiotics, anti-diarrheals and tonics, interrupting any demand-side pull to reshape the market.

As seen from the factors influencing the current market failure, the desired shift to ORS and zinc as the primary diarrhea treatments will require a coordinated effort amongst stakeholders across sectors to mitigate private sector risks for the achievement of public sector objectives. Notably, this includes looping RMPs, the most common source of diarrhea treatment in India, into the flow of health information and engagement that extends beyond didactical training to influence changes in prescribing behavior. In addition, repositioning ORS and zinc through innovative marketing tactics that draw on key behavior change insights will support redefining the most appropriate treatment for diarrhea in the country. This may include the introduction of a co-package product of ORS and zinc that can directly compete with alternative treatments on price and profitability.

While the public sector has a role in creating awareness and establishing credibility for ORS and zinc as the primary treatment for diarrhea, this assessment reinforces the centrality and great potential of the private sector, as well as the challenges within this market that need to be addressed to achieve national diarrhea treatment targets.

²²⁴ UNICEF. “Management Practices for Childhood Diarrhea in India.” 2009