



# Assessment of the gastrointestinal (GI) market

*Case study*

# BA developed a market assessment for gastrointestinal (GI) primary care in emerging markets for a global pharmaceutical company

## Client Background

- The client is a leading pharmaceutical company headquartered in France and offers a diversified portfolio of drugs in both specialty and primary care. It has presence across more than 100 countries, with annual revenue of over €1B
- The client sought to increase revenue of its primary care business with the launch of its GI portfolio<sup>(A)</sup> in five emerging markets – Brazil, India, Saudi Arabia, Turkey, and the UAE

## Key Highlights

- **Project Scope:** BA delivered an in-depth understanding of the markets and therapy-specific opportunities based on following parameters:
  - **Disease Overview:** Prevalence rate, diagnosis, and treatment along with patient treatment pathways to identify market needs and key influencers in driving prescription and purchase behavior
  - **Market Assessment:** Opportunity size by disease, therapeutic area, and retail channel addressing any differences by geographic concentration and /or customer segment
  - **Competitive Landscape:** Key players' market share, product portfolio, positioning, pricing, and route-to-market (RTM)
  - **Channel Analysis:** Distribution models, activities, and margins; retail and institutional landscape and role in targeting different customer segments
  - **Regulations:** Policies and processes shaping opportunity and strategy for market entry and commercialization including business model, licensing and registration, pricing, reimbursement, labeling, marketing and advertising, and more
  - **Healthcare Infrastructure:** Overview of healthcare infrastructure by country with analysis on availability and accessibility of specialized GI- specific services
- **BA Approach:** BA conducted an extensive literature review and a detailed in-country primary research with key stakeholders (including government officials, pharmaceutical companies, distributors, retail channel entities, physicians, pharmacists, and experts) across all five countries and multiple cities. This enabled the client understand the nuances of operating and succeeding in these countries
- **Outcome:** BA delivered a comprehensive assessment of the market opportunity and recommended go-to-market and route-to-market strategies which helped the client secure Board approval for market entry and portfolio commercialization. BA's work included recommendations on an optimal market entry model, projected timeline, commercial organization structure, therapeutic priorities, and patient segment targets, enabling the generation of new revenue streams

## Key Business Questions



Note:

(A) GI diseases under scope: Diarrhea, Constipation, Irritable Bowel Syndrome (IBS), Bowel Cleansers, Ulcerative Colitis, Crohn's Disease and GERD

# Disease prevalence, diagnosis and treatment rates were studied to determine market opportunity across each market

1

What is the current and future market opportunity for GI drugs? Which therapies offer the best potential? What is the opportunity for Rx vs. OTC classification and sales?

2

What are the key market regulations? Which business model is most efficient and will best ensure successful commercialization?

3

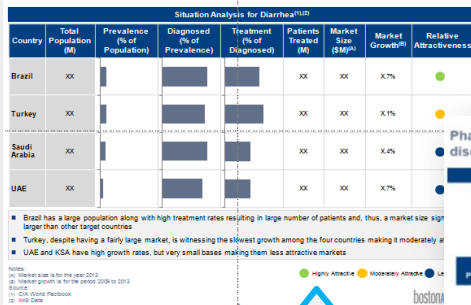
What are the competitive dynamics by therapy area? Who are the market leaders and how are they structured? What are their core strategies?

4

How is institutional and retail pharmacy trade structured? Which channels are most attractive and how can they best be penetrated? What is the best RTM?

Prevalence of diarrhea ranges between X%-XX% among countries with diagnosis rate of XX% or higher

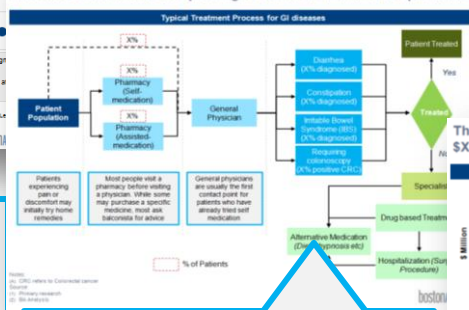
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BA analyzed the prevalence, diagnosis and treatment rates of GI diseases across five countries to provide both a localized and comparative view of market attractiveness. This helped the client understand each of these markets and prioritize and target the most attractive opportunities

Pharmacies and general physicians are first line of care for GI diseases while severe and prolonged cases are referred to specialists

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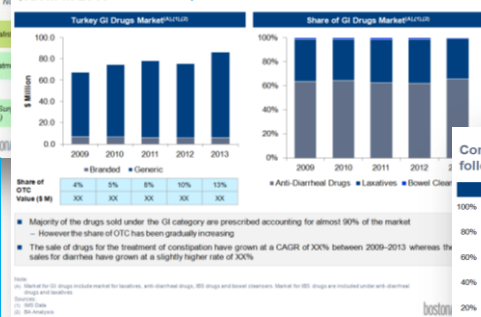


BA defined the typical patient treatment pathway, mapping the role of healthcare facilities and providers involved. BA identified the stakeholders influencing treatment and drug purchase decisions to enable the client to determine where to develop strategic relationships

BA quantified the size of the GI drugs market and of each therapeutic area for each country. BA provided a view on fundamentals of market structure, including the share and perception of branded vs. generic drugs, OTC vs. Rx drugs

The market for relevant GI drugs grew at a CAGR of 6.5% in 2013

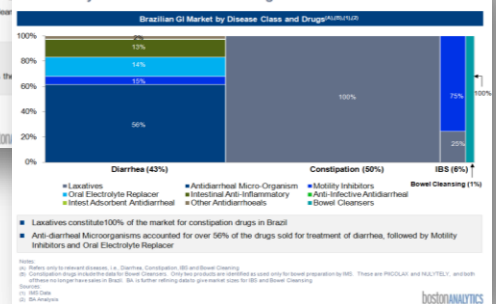
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BA provided a cross-sectional analysis of the GI market by disease and determined treatment and drug prescription patterns to help define and contextualize the market opportunity for the client

Constipation drugs is the biggest segment among targeted followed by anti-diarrheal and IBS drugs

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# Regulatory factors required for commercialization of products and evaluated the business model for fastest market entry were studied

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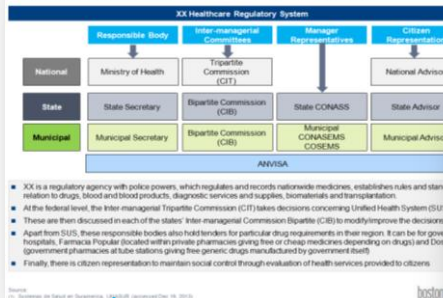
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XX uses a multi-level regulatory system in healthcare, autonomy to states and municipalities in policy making

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Any new drug supplier must obtain an import license for products with ANVISA which takes up to 12 months

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Criteria	Sub-Criteria	Regulations	Appeal
Company and Product Registration		<ul style="list-style-type: none"> <li>There are two types of regulation of products by ANVISA. Initially, a company needs to register to get license for operating in Brazil. For the same, it must have a direct presence in Brazil or a "responsible" company.</li> <li>Post that, each product needs to be listed with ANVISA. For listing, drugs are analyzed by ANVISA which takes between 6-12 months for OTC drugs.</li> <li>Each OTC product needs to be re-registered every five years.</li> <li>Each variant of dosage of the OTC drug needs to be registered separately.</li> </ul>	
Market Entry		<ul style="list-style-type: none"> <li>To apply for marketing authorization, the manufacturer must have a valid GMP certificate.</li> <li>Further, to import OTC drugs, companies need to apply for import permit and annual import quota with ANVISA which is valid for one year.</li> <li>Import duties on medicines range from 3%-17%, depending on the active substance.</li> <li>ANVISA has approved a system that will be used to track drugs from manufacture to point of sale.</li> </ul>	

BA defined the implications and risk of international reference pricing and compulsory licensing according to individual country requirements and precedents

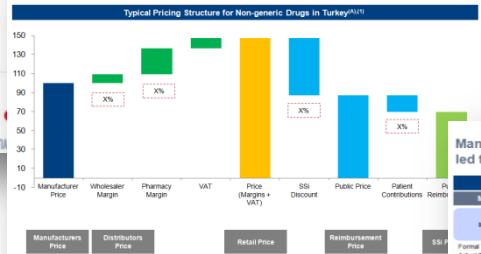
BA weighed all market entry options with associated steps and timelines for approvals to determine the most attractive and efficient market entry model

BA identified and mapped the agencies that regulate the pharmaceutical industry and drug approval in each country. BA defined the scope of their role and influence in the regulatory process. It estimated the expected time for commercialization based upon multiple scenarios, including a view of official and actual approval timelines

BA analyzed key regulatory steps related to commercialization of the client's product, including licensing and registration, facility inspection, pricing, reimbursement, labeling, promotion, etc.

Typical pricing structure of non-generic drugs in Turkey

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Mandatory inspection of manufacturer's facility in other countries led to a long waiting time for entry of drugs through import in Turkey

Model	Regulatory Procedures/Steps	Total Time
Import	GMP certification and inspection, Registration, Product Pricing and Market Authorization, Sales Permission, Reimbursement	OTC: 36-48 months Rx: 36-48 months 14 months for reimbursement
Regulatory Local Manufacturing	GMP certification and inspection, Registration, Product Pricing and Market Authorization, Sales Permission, Reimbursement	OTC: 18-24 months Rx: 18-24 months 14 months for reimbursement
Contract Manufacturing through local partner	GMP certification and inspection, Registration, Product Pricing and Market Authorization, Sales Permission, Reimbursement	OTC: 18-24 months Rx: 18-24 months 14 months for reimbursement

■ In Turkey, it is difficult to obtain regulatory approvals for a human medicinal product considering the lengthiness of the regulatory process, various regulatory rules and approval criteria.

■ Having a local manufacturing presence is beneficial as it may reduce the market entry timelines considerably.

Note: GMP certification details for Contract Manufacturing Practices in local manufacturing. GMP certifications are required to be taken before the facility is set up. Source: (1) Pricing request with representation by SS, a division of Pfizer. (2) Patient Access to Innovative Medicines. <http://www.pfizer.com/patient-access>. Accessed on Jan 23, 2016.

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# BA identified leading players within drug categories, RTM for targeting retail and institutional customers and pricing analysis

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Leading therapeutic segments such as anti-diarrheal are characterized with low market concentration

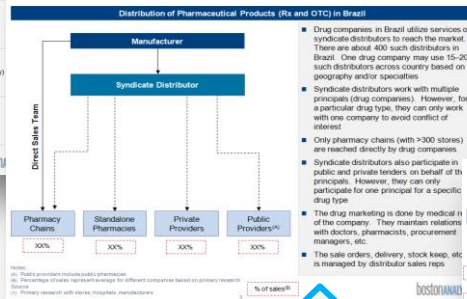
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Therapeutic Area	Market Size (\$M) <sup>(1)</sup>	Market Concentration <sup>(2)</sup>	Key Players (% Share) <sup>(3)</sup>	Key Brands (Treatment cost per day, \$) <sup>(4)</sup>
Anti-ulcerant	HRH: 420		<ul style="list-style-type: none"> <li>Dr. Reddy's</li> <li>Sun Pharma</li> <li>Canva</li> <li>Zydus Cadila</li> <li>Others</li> </ul>	<ul style="list-style-type: none"> <li>Omez (\$/day)</li> <li>Pantocid-D (\$/day)</li> <li>Pan D (\$/day)</li> </ul>
Anti-diarrheal	HRH: 332		<ul style="list-style-type: none"> <li>Marketed</li> <li>Dr. Reddy's</li> <li>Sun Pharma</li> <li>Canva</li> <li>Zydus Cadila</li> <li>Others</li> </ul>	<ul style="list-style-type: none"> <li>C2 (\$/day)</li> <li>Norflex TZ (\$/day)</li> <li>Zenoflex HT (\$/day)</li> </ul>
Antacids and Antiflatulents	HRH: 1,533		<ul style="list-style-type: none"> <li>Pfizer</li> <li>Abbott</li> <li>Alkermes</li> <li>Boehringer</li> <li>Others</li> </ul>	<ul style="list-style-type: none"> <li>Digene (\$/day)</li> <li>Geftal (\$/day)</li> <li>Ugel (\$/day)</li> </ul>
Laxatives	HRH: 1,838		<ul style="list-style-type: none"> <li>Abbott</li> <li>Zydus Cadila</li> <li>Sun Pharma</li> <li>Canva</li> <li>Others</li> </ul>	<ul style="list-style-type: none"> <li>Diphacat (\$/day)</li> <li>Cremalin Plus (\$/day)</li> <li>Dulcolex (\$/day)</li> </ul>
Bowel Cleaners	HRH: 3,306		<ul style="list-style-type: none"> <li>Tablets India</li> <li>Marketed</li> <li>Dr. Reddy's</li> <li>Sun Pharma</li> <li>Canva</li> <li>Others</li> </ul>	<ul style="list-style-type: none"> <li>Gudlak Plus (NA)</li> <li>Peglec (NA)</li> <li>Dulcolex (NA)</li> <li>Exaltel (NA)</li> </ul>

Source: (1) HRH 2016; Primary research with pharmaceuticals; (2) HRH 2016; Primary research with pharmaceuticals; (3) HRH 2016; Primary research with pharmaceuticals; (4) HRH 2016; Primary research with pharmaceuticals

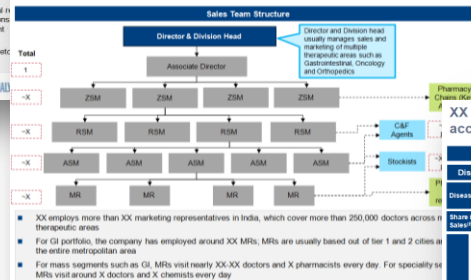
Manufacturers utilize large syndicate distributors to penetrate relevant outlets and geographic areas in Brazil

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BA identified the sales and distribution team structure for the leading players in each country to enable the client to help define the optimum team size and structure

Illustrative



BA studied the product portfolio, pricing, strategy, and key success factors of leading companies to help the client understand its competitive position

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XX GI portfolio consists primarily of laxatives; bowel cleaners account for an insignificant share

Dispensing Mode	Prescription	OTC	Total
Disease Class	Constipation (Laxatives)	Colonoscopy (Bowel Cleaners)	NA
Share in Company GI Sales <sup>(1)</sup>	3%	NA	3%
Brand	3 Variants (Oral Liquid 200MG, 150MG; Suspension 100MG, 150MG; Tablets 20MG)		3%
B.T. Crema	1 Variant (Crema Liquid)		3%
XX Kolor <sup>(2)</sup>		1 Variant (Cough Syrup 900mg)	NA
B.T. Oral		1 Variant (Oral Liquid)	3%

BA analyzed the market share of companies within each drug category (e.g. laxatives) and the cost of treatment for top drugs to help the client develop an estimate of potential revenue by country, by product

BA studied the Go-To-Market (GTM) and Route-To-Market strategies of the top 3 players in each country, differentiating between institutional and retail pharmacy channels

# The distribution and retail landscape were analyzed to recommend a profitable RTM roadmap for each country

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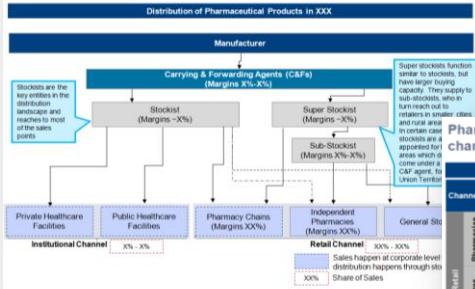
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Pharma distribution involves multiple entities and stakeholders in delivering supplies to the retail channels

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Pharmacies account for more than XX% of sales and are a key channel for drug distribution

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Channel	Retailers	Regional Presence	Product Portfolio	Margins	Procurement	No. of Entities	Share in relevant GI
Pharmacies	Standalone Pharmacies	Rural	All Drugs (Branded & Generic)	100%	50/50	XX	100%
	Pharmacy Chains	Urban	All Drugs (Branded & Generic)	100%	50/50	XX	100%
	Modern Trade (MT) Outlets	Urban	Apuronic and Herbal Products	100%	50/50	XX	100%
	General Stores	Urban	Apuronic and Herbal Products	100%	50/50	XX	100%
General Stores	Pharmacy Chains	Rural	Apuronic and Herbal Products	100%	50/50	XX	100%
	Modern Trade (MT) Outlets	Urban	Apuronic and Herbal Products	100%	50/50	XX	100%
	General Stores	Urban	Apuronic and Herbal Products	100%	50/50	XX	100%
	Pharmacy Chains	Urban	Apuronic and Herbal Products	100%	50/50	XX	100%
Independent Pharmacies	Standalone Pharmacies	Rural	Mostly Generic drugs	N/A	50/50	XX	100%
	Pharmacy Chains	Urban	Mostly Generic drugs	N/A	50/50	XX	100%
	Modern Trade (MT) Outlets	Urban	Mostly Generic drugs	N/A	50/50	XX	100%
	General Stores	Urban	Mostly Generic drugs	N/A	50/50	XX	100%
General Stores	Standalone Pharmacies	Rural	Mostly Generic drugs	N/A	50/50	XX	100%
	Pharmacy Chains	Urban	Mostly Generic drugs	N/A	50/50	XX	100%
	Modern Trade (MT) Outlets	Urban	Mostly Generic drugs	N/A	50/50	XX	100%
	General Stores	Urban	Mostly Generic drugs	N/A	50/50	XX	100%

BA studied the sales and distribution structure used by pharmaceutical companies in each market to assess both institutional and retail pharmacy customers. BA determined the contribution, margin and role by channel entity

BA mapped the role of each retail entity, degree of influence on patients (customers), manufacturer enlisting criteria, and procurement process while highlighting key regional differences

BA studied manufacturers' activities with respect to each channel entity to understand how they can be incentivized to sell the client's products

A company's promotion representative plays a pivotal role in maintaining relationship with pharmacies and pushing

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Criteria	Role of Manufacturer
Drug Enlisting	<ul style="list-style-type: none"> <li>Product listed with HQ pharmacy chain. It is listed out at several stores by HQ and eventually added to a regular purchase list based on demand for the drug</li> <li>Samples are given to standalone pharmacies and repurchases are done based on demand</li> <li>Pharmacies are visited by promotion representatives fortnightly or monthly to showcase new products and maintain relationships</li> </ul>
Pharmacy Visits	<ul style="list-style-type: none"> <li>Because balconia is the main influencer for OTC sales, companies target it for incentives. Balconia receives target-based cash incentives, e.g., sell 2,000 boxes for 8% cash bonus</li> <li>Balconia and designated pharmacist also receive sample gifts like branded pens, watches, etc.</li> <li>Pharmacy chains also have marketing agreements with manufacturers under which their products are sold at 30-40% discounts in exchange to shelf space, higher visibility and promotions or pharmacy chain's leaflets and websites</li> </ul>
Incentives	<ul style="list-style-type: none"> <li>Companies also provide marketing material - for which the pharmacies may give space but charges and agreements</li> </ul>
Marketing	<ul style="list-style-type: none"> <li>Although no formal training is given by manufacturers to balconia or pharmacists, the prior reps usually introduce products, provide correct dosage and usage directions in an informal manner. Companies do not give MSL support to pharmacies. However, there are certain common on placement sites such as www.pharmatalk.com or that are used by small pharmacies. Pharmacies have their own automatic ordering systems</li> <li>Some pharmacies support distributor sales reps in maintaining PoS design and layout</li> <li>Pharmacies also sell generic drugs for OTC drugs e.g. Paracetamol - \$100 for 1m<sup>3</sup> for 1m<sup>3</sup></li> <li>No pharmacies have exclusivity agreements with manufacturers</li> <li>A major role of promotion reps is also to collect competitor data - about new drugs, sales, etc. They also collect information about the type of patients visiting and their drug preferences</li> </ul>
Trainings	
MSI/Software support	
PoS Layout	
Exclusivity	
Intelligence	

BA developed a market entry roadmap with details on prioritized target markets, business model, organizational structure, and channels to leverage

XX may need XX-XX MRs to reach out to retail channels and physicians across XX

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Therapeutic Areas	Market Size (\$M)	Recommended Organization Structure
Markets to Consider	<ul style="list-style-type: none"> <li>Diabetes</li> <li>Complication</li> </ul>	<ul style="list-style-type: none"> <li>Owner/ Business Unit Head</li> <li>Zone Sales Manager</li> <li>Area Sales Manager</li> <li>Medical Representatives</li> </ul>
Share of Rx vs OTC (GI market)	<ul style="list-style-type: none"> <li>OTC</li> </ul>	
Share of Branded vs Generics	<ul style="list-style-type: none"> <li>Generics</li> <li>Branded</li> </ul>	
Regulations	<ul style="list-style-type: none"> <li>Shortest time to Market: Contract manufacturing through local partner (15 Months)</li> <li>Price Controls: 16 (2 molecules are price regulated including branded)</li> <li>C&amp;F Agents: 1-3 per state</li> <li>Rebates: ~2,500</li> </ul>	
Distribution	<ul style="list-style-type: none"> <li>Retail Channel: Standalone pharmacies (750,000) &amp; chains (5,000)</li> </ul>	
Retail Channel	<ul style="list-style-type: none"> <li>With 3% of the drugs sold being Rx, generating prescriptions through doctors is key to winning in the Indian GI market</li> </ul>	

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