



# Competing with 'Generics'

*Life Sciences Practice*  
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**UC** Life Science  
Consulting

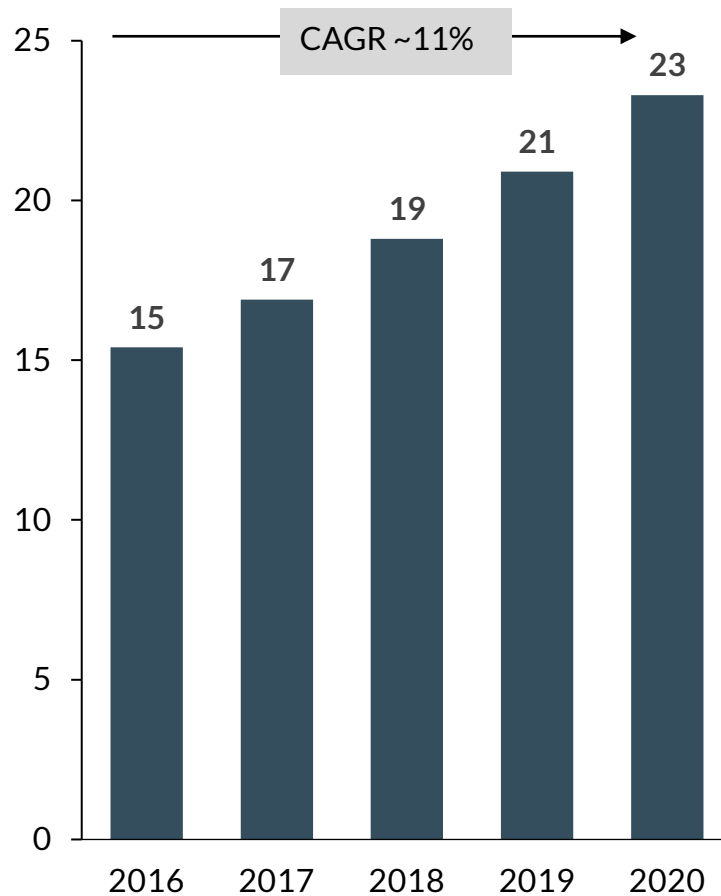
# The Indian Pharma Market is witnessing a drive towards “genericisation”

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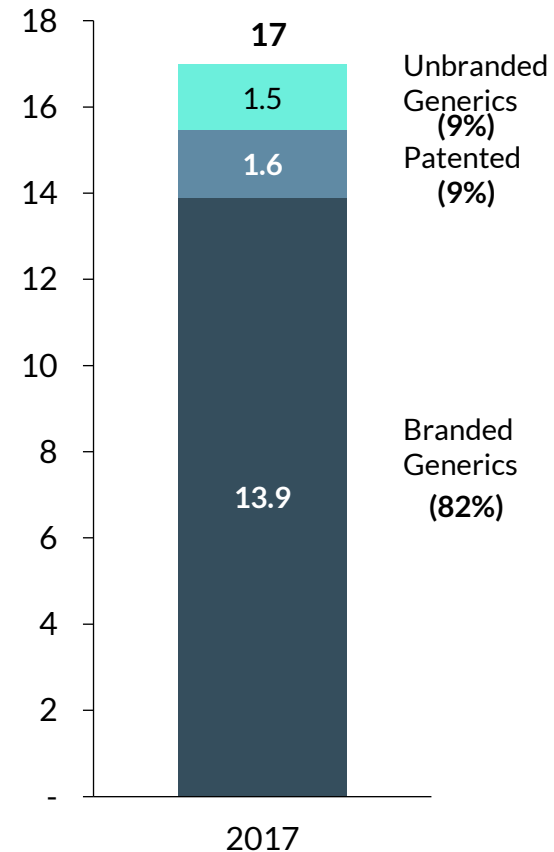
- The USD 17bn Indian pharma market, currently dominated by Branded Generics, is witnessing a drive towards generics
- Developed markets like the USA, UK, Germany and Canada have evolved towards genericisation to reduce cost of healthcare. These markets have instituted a number of supplementary policies like prescription policies, physician incentives etc. to drive genericisation
- The Indian government is propagating generics through various initiatives like Jan Aushadhi. Initiatives taken by states such as Rajasthan, Kerala and West Bengal are already driving generics usage. Further, with the roll-out of the National Health Protection Scheme, the usage of generics is set to increase
- Market modelling of different scenarios indicates a rise in the generics segment:
  - If there is public adoption of generics - penetration in the market will increase from 9% to 15.5%
  - If all drugs under NLEM are genericised – generics penetration in the market will increase from 9% to 21%.
- Further, genericisation may drive consolidation; many small players may not be able to survive the stringent regulations, while large players will strengthen generics presence through acquisitions.

# The USD 17 bn Indian pharma market is dominated by Branded Generics (2017)

**Indian Pharma Market**  
USD bn<sup>1,2,3</sup>



**Market Segments**  
USD bn<sup>1,2,3</sup>



Note: Unbranded generics market share has been derived by deducting the share of branded generics and patented drugs from total market

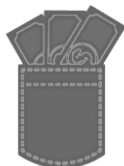
Source: <sup>1</sup>Primary Research, <sup>2</sup>Indian domestic pharma market is estimated at Rs 90,400 crore ending FY15: IBEF, EP News Bureau, 11<sup>th</sup> Sep, 2015, <sup>3</sup>Generics to double in 5 years, The Hindu, 12<sup>th</sup> Sept, 2015;

# Healthcare expenditure is a major challenge in India



## ~80% of Population not covered by Insurance<sup>5</sup>

- ~ 86% of the rural population and ~82% of the urban population were not covered under any scheme of health insurance
- ~12% of the urban and ~13% of the rural population covered by Government funded insurance



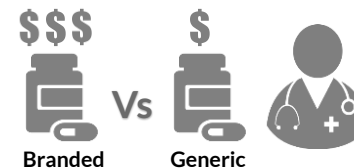
## High Out of Pocket expenditure on Medicines<sup>1,2</sup>

- Spending on healthcare expenditure in India is mainly OOPPE (~68% in urban India and 72% in rural areas)
- ~70% of total healthcare expenditure on medicines (2014)



## Major Cause of Poverty<sup>1,2</sup>

- Between 2004 - 2014, average medical expenditure increased ~170%
- 63 million people plunge into poverty annually due to healthcare costs



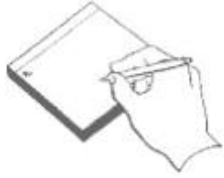
## Branded Generics costlier<sup>2</sup> and popularity linked to perceive Doctor-Pharma Nexus<sup>3,4</sup>

- Branded/Branded generics are 50-60% more expensive than generics
- Branded Generics companies promote their drugs through doctors

Source: <sup>1</sup> India's aspiration for universal health coverage, The New England Journal of Medicine, 2015, <sup>2</sup> The astonishing cost of healthcare in India, Quartz India, 18<sup>th</sup> April, 2016, <sup>3</sup> Doctor-pharma firms' nexus runs deep, The Times of India, 8<sup>th</sup> May, 2015, <sup>4</sup> Welcome to India, the Land of the Drug Reps, Bloomberg, 9<sup>th</sup> Sept, 2011, <sup>5</sup> Health cover: Too little, too scarce, The Hindu, 12<sup>th</sup> Apr, 2016



# The government is propagating generics to reduce healthcare expenditure



## Physicians to be Legally Mandated to Prescribe Generics

- Medical Council of India (MCI) circular (29th September, 2016) – directing all Registered Medical Practitioners to prescribe drugs (with generic names mentioned)
- Central government working on amending Drugs and Cosmetics Act to make it mandatory for physicians to prescribe generic name of the drug ( 18th April, 2017)



## Generic Names to be Displayed Conspicuously

- Union health ministry amends the labelling section in Drugs and Cosmetics Rules (2017)
- Mandatory for pharma companies to mention generic names in font twice the size of branded name (early 2017)



## Requirement of BA/ BE Studies for certain Drugs

- Generic manufacturers not required to conduct BA/ BE studies, 4 years after first approval
- Amendment to the Drugs and Cosmetics (Ninth Amendment) Act, mandates generic players to conduct bio-equivalence tests for some generic drugs (April 3<sup>rd</sup>, 2017)

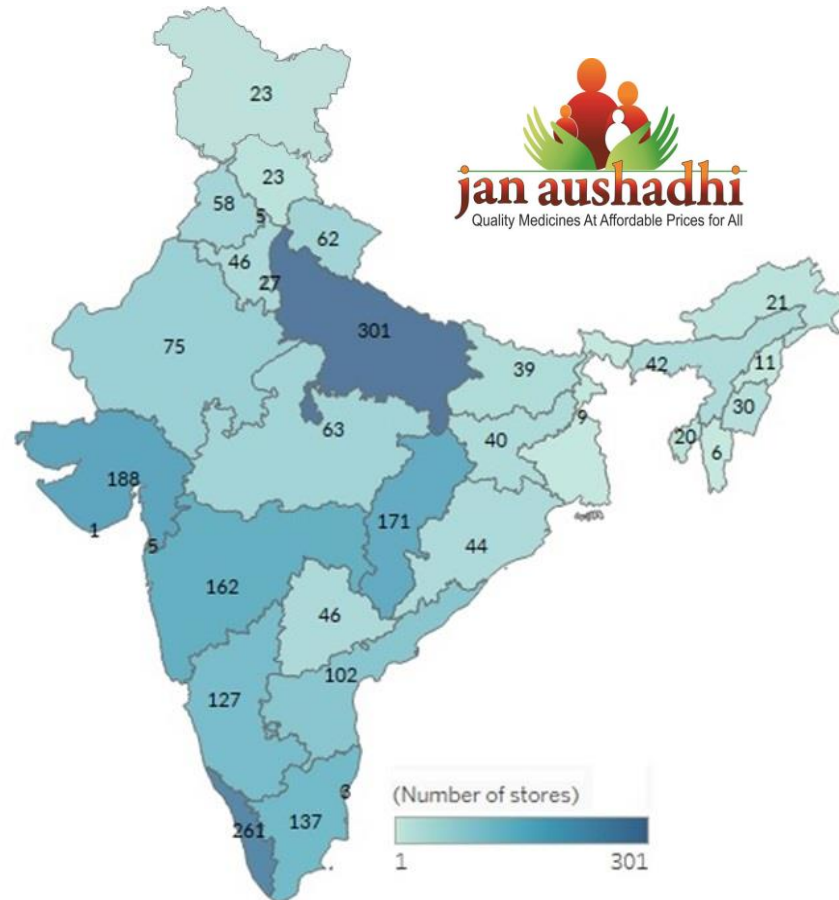


## Pharmacies to have a Separate Rack Conspicuously for Generics

- The Drug Technical Advisory Board (DTAB) agreed to keep separate shelves solely for generics drugs which shall be visible to the consumers
- Government is considering a proposal to allow pharmacists to sell generic version of the drug if the doctor prescribes the branded alternative

# Government is expanding Jan Aushadhi stores (PMBJP scheme) to improve access to affordable generics

## Jan Aushadhi Stores<sup>1</sup>



Access to quality drugs at affordable price<sup>1</sup>

- Drugs procured from CPSU (Central Procurement and Supply Unit) and private suppliers
- Medicines are tested from NABL approved lab

Access to land/capital for setting up store<sup>1</sup>

- INR 2.5 Lacs is provided to either a public/private body to open stores
- State government to provide space

Undertaking expansion to improve coverage<sup>1</sup>

- Before 2017, it was around 700 stores and currently 3000+ stores nation-wide
- Plans for Jan Aushadhi stores in 1,000 major railway stations<sup>2</sup>

Note: PMBJP - Pradhan Mantri Bhartiya Janaushadhi Pariyojana, NABL - National Accreditation Board for Test and Calibration Laboratories

Source: <sup>1</sup> www.janaushadhi.gov.in/, 2<sup>nd</sup> August, 2017; <sup>2</sup>Govt plans to open Jan Aushadhi stores at 1k railway stations, The Times of India, 22<sup>nd</sup> May, 2017

# Rajasthan, Kerala and West Bengal have taken initiatives to promote Generics



## Rajasthan<sup>1</sup>

- Rajasthan Medical Services Corporation (RMSC) has facilitated the use of generics since 2011
- 90% + prescriptions in generics through ~15000 drug distribution outlets (hospitals, medical college, community health center, etc.)
- Procurement by e-bidding (quality control inbuilt in the procurement process)



## Kerala<sup>2</sup>

- Kerala Generics initiatives launched on 1st April 2017
- ~54 Karunya Community Pharmacy outlets expected to store at least three variants of generics
- Karunya Community Pharmacies provide 20-60% discounts on the price of branded generics

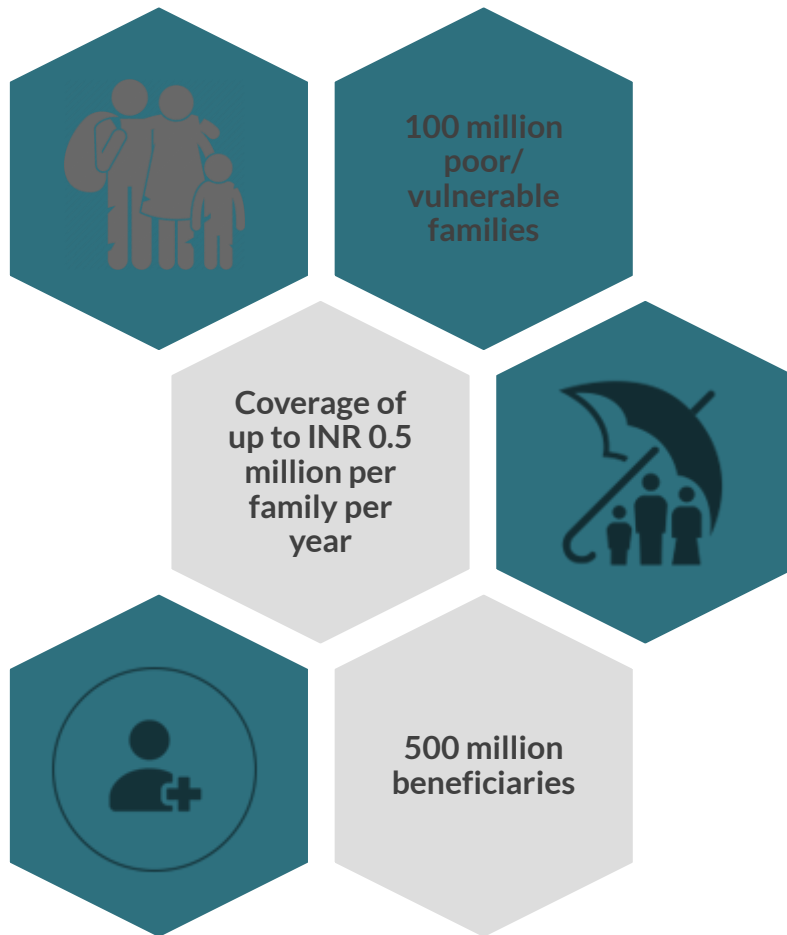


## West Bengal<sup>3</sup>

- Launched Fair Price Medicine Shops (FMPS) to provide affordable quality medicines (2012)
- INR 585 crore+ medicines sold through more than 150 medicine shops
- Discounts of 48% -77% provided

Source: <sup>1</sup>Rajasthan, India – Pharmaceuticals in Health Care Delivery, World Health Organization, 2013, <sup>2</sup>State to move towards generic drugs, The Hindu, 4<sup>th</sup> Feb, 2017, <sup>3</sup><http://aitcofficial.org>, 1<sup>st</sup> March, 2016

# National Health Protection Scheme announced in Budget 2018 aims improving affordability



**INR 2,000 crore allocated for NHPS**

- In Budget 2018, the government has allocated an amount of INR 20 billion
- The Centre will bear 60 % of the cost while 40 % will be borne by the states

**NHPS to reach 50% beneficiaries in 2019**

- NITI Aayog estimates NHPS to reach 50 % beneficiaries in 2019
- INR 1200 billion to be paid as premiums to private health insurance firms to extend coverage to 500 million people

**Focus on Quality Generics**

- Department of Pharmaceuticals emphasised that the scheme will adopt quality generic medicines in a meeting with CEOs of MNCs and large domestic players



# Developed and emerging markets have evolved towards genericisation

Country	% Generic (By Volume)	% Generic (By Value)	Total Pharma Market Size
USA	84%	28%	\$339 bn
UK	83%	33%	\$24 bn
Germany	80%	37%	\$45 bn
Canada	70%	29%	\$21 bn
Spain	47%	21%	\$20 bn
Chile	80%	59%	\$2.3 bn
New Zealand	77%	34%	\$1 bn
Turkey	55%	37%	\$8 bn
Finland	40%	17%	\$2.3 bn
China	90%	64%*	\$108 bn
Philippines	56%*	13%*	\$3.40 bn
Vietnam	77%	51%	\$3.50 bn
India	75%	9% (unbranded generics)#	\$17 bn

Note: \* 2012 data; # Indian market is dominated by Branded Generics (~82% of the overall market)

Source: [www.worldatlas.com](http://www.worldatlas.com), 2<sup>nd</sup> August, 2017

# India also needs to consider other supplementary policies to drive genericisation

	India	USA <sup>1</sup>	UK <sup>1,2</sup>	Germany <sup>1,2</sup>	Finland <sup>1,2</sup>	Sweden <sup>1,2</sup>	France <sup>1,2</sup>
<b>Market Size</b>	\$17 bn	\$333 bn.	\$37 bn.	\$60 bn.	\$2.3 bn.	\$4 bn	\$34 bn
<b>Prescription Policy</b>	Proposed policy for generic prescription	INN/ Generic encouraged	Mostly INN/Generic encouraged	INN/Generic encouraged	INN/Generic encouraged	No generic prescription policy	INN/Generic encouraged
<b>Generic Substitution</b>	On ad hoc basis by retailer	Yes	No	Yes	Yes	Yes	Yes
<b>Regulated Pricing</b>	Regulated pricing*; Free pricing for non NLEM drugs	No	No	Regulated pricing for in-patient drugs only**	Yes	No	Yes
<b>Physician Incentives</b>	No	No	Yes	Yes	No	No	Yes
<b>Pharmacist incentives</b>	No	No	Yes	Yes	No	NA	Yes
<b>Formulary</b>	No #	Yes	Yes	Yes	Yes	Yes	Yes

Practiced
  Not practiced
  Partial implementation

Note: \* Prices are capped with reference to prices of companies with more than 1% market share, # National Formulary of India is not approved by regulatory body for use as a reference for generic substitution, \*\* - mainly a tender-driven market; NA - Data not available

Source: Primary Research, <sup>1</sup> The experiences of implementing generic medicine policy in eight countries, Saudi Pharmaceutical Journal, 2014, <sup>2</sup> European market entry strategy for generic companies, European Commission, 2016

# In the context of the proposed policies, different scenarios may impact market dynamics

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## Scenario A

What if the public healthcare sector completely adopts generic medicines?

## Scenario B

What if all the drugs under NLEM are genericised?

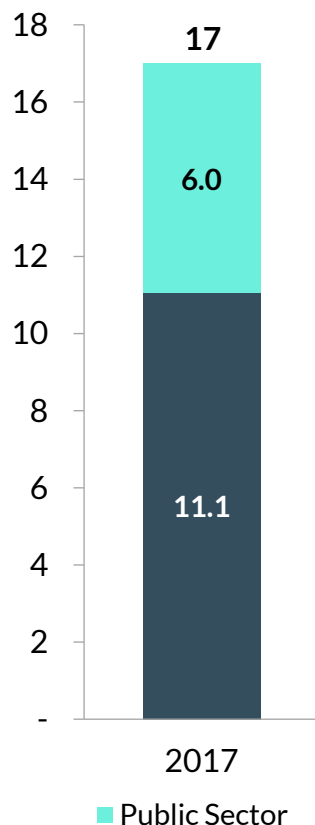
## Scenario C

Likelihood of consolidation in the Indian pharma market?

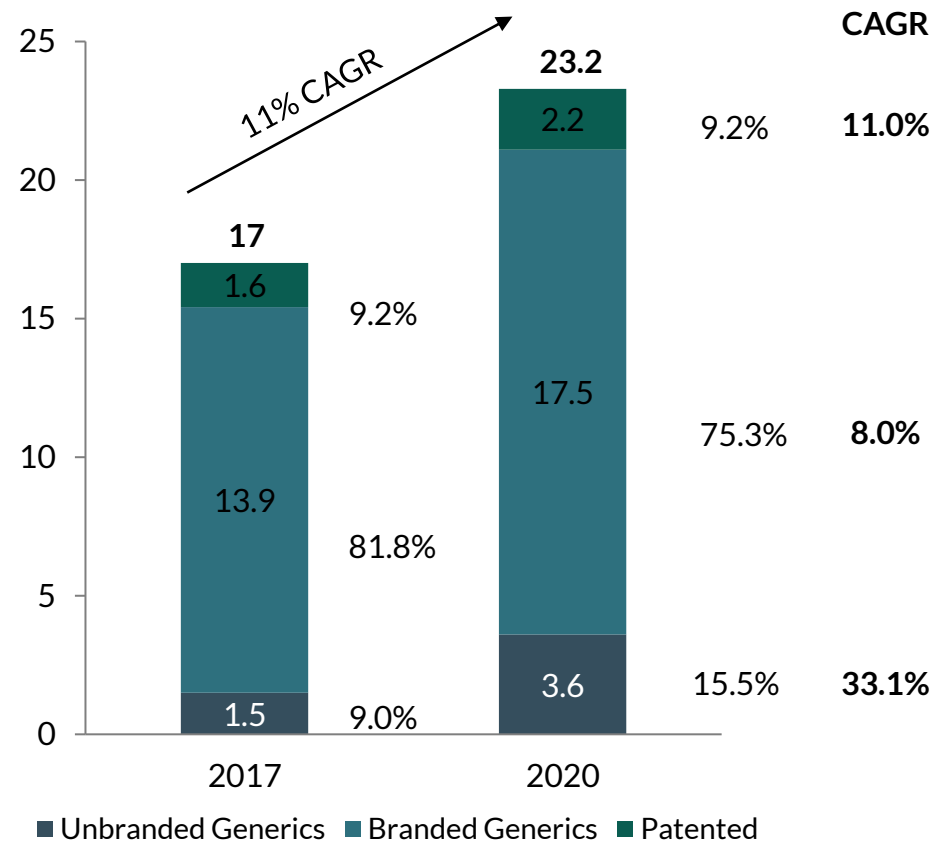
# Scenario A - What if the public healthcare sector completely adopts generic medicines?

Indicative

Indian Pharma Market  
USD bn



Segmentation of Indian Pharma Market by Value  
USD bn



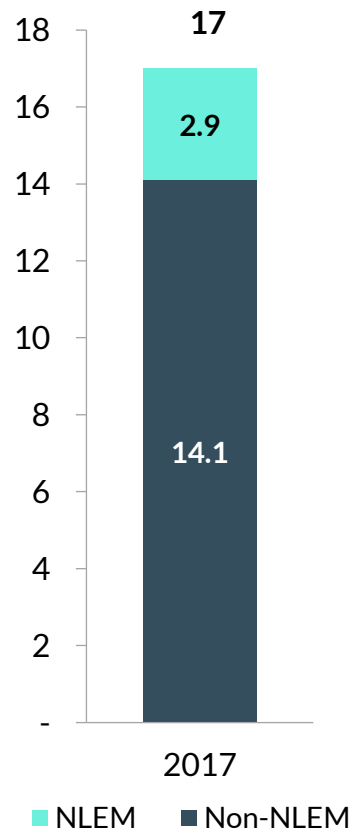
If there is public adoption, then generics penetration will increase from 9% to 15.5%

Note: Overall contribution of public sector by value is expected to go down  
Source: Primary Research, UC Analysis

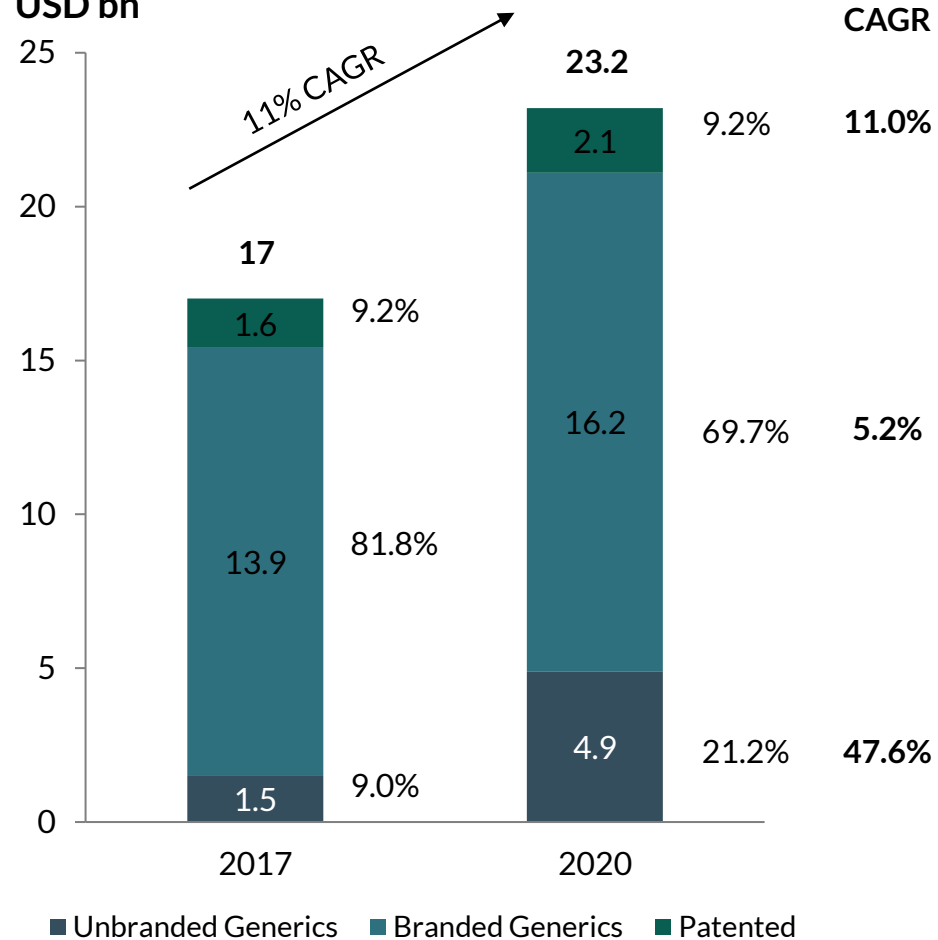
# Scenario B - What if all the drugs under NLEM are genericised?

Indicative

Indian Pharma Market  
USD bn



Segmentation of Indian Pharma Market by Value  
USD bn



If all drugs under NLEM are genericised, then generics penetration will increase from 9% to 21%

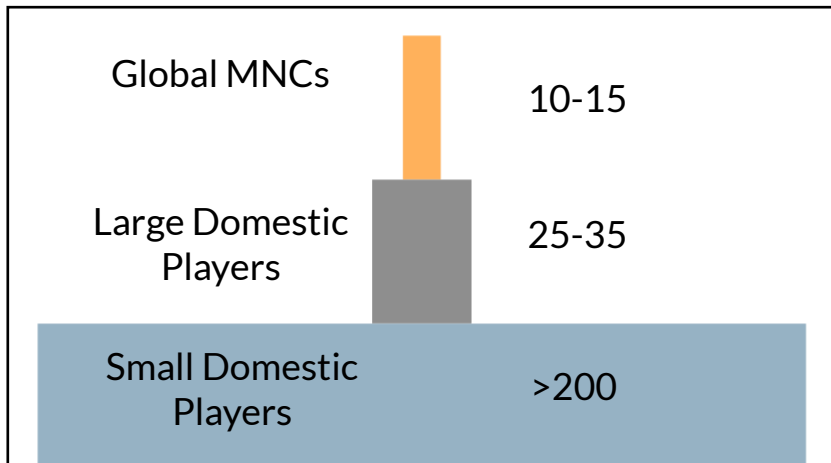
Source: Primary Research, UC Analysis



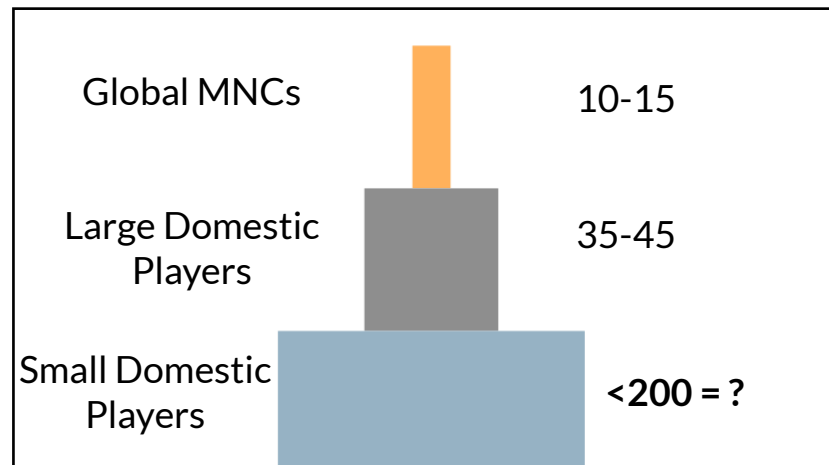
# Scenario C - Likelihood of consolidation in the Indian pharma market?

Indicative

## Current Scenario\*



## Post Genericisation\*



Genericisation strategy will challenge smaller industry participants and lead to consolidation

Stringent regulations may lead to consolidation

Large players will strengthen generic capabilities through acquisition

- Enforcement of strict regulatory guidelines for approval and quality control is likely to pose a challenge to small pharma companies, resulting in mergers, acquisitions in the industry or some players going out of business  
*"...with government mandating BA/BE studies, small domestic players may not be able to afford the costs associated with these studies.."*  
*Industry Expert*

*"..If the genericisation and other regulatory policies are implement stringently, the number of pharma companies will reduce to 100-150 from ~500 as a result mergers and acquisition or survival challenge.."*

*Industry Expert*

- Large Indian players and MNCs will strengthen their generics capabilities through acquisition of small generics players  
*"...large Indian players and MNCs, who till date, have majorly focused on Branded Generics will be looking to acquire small generic players to quickly boost their generics capabilities. This will also result in an increase in average player revenue.."*  
*Industry Expert*

Note; \* - Width of the bar indicates the number of players in this space, Large Indian Players - Players contributing >0.5% to Indian Pharma Market, # Small Indian Players - Players contributing to <0.5% to Indian Pharma Market

Source: Primary Research, UC Analysis

# Competing in the age of generics will require Indian Pharma companies to deploy “Four Strategies”



Note: <sup>1</sup>.OTC-Over the counter  
Source: UC Analysis

# Strategy One - Expand OTC portfolio (OTC and Differentiated Generics products)

## 1.1

### Establish OTC Engine

- Develop OTC Engine to facilitate identification of products
  - *Boehringer Ingelheim successfully managed the transition of its flagship brands Dulcoflex and Buscogast in an OTC market with unmet needs*
  - *Heritage Rx brands such as Revital and Crocin, with strong medical equity, have switched to OTC*
- Launch differentiated formulations
  - *"... niche formulations like injectables are in demand due to difficulty in formulations. Intensity of competition for these formulations is lower than regular OSDFs ..."*

## 1.2

### Explore New Channels

- Tie-up with e-commerce portals like Amazon, Flipkart, etc. to cater to order bookings
  - *Modern trade channels like D-Mart, Big Bazaar, etc. to push for product sales and increased visibility*
  - *Partner with FMCG companies to drive reach of OTC products for e.g. Pfizer has partnered with ITC for OTC portfolio*

## 1.3

### Strategise Marketing Spend

- Typically, OTC products require 10-20% of revenue as marketing expenditure vs 3-8% for Rx products
  - *About 16-19% of the revenue for key OTC brands like Eno, Himani and Vicks have been spent on marketing expenditure<sup>1,2,3</sup>*
- Strategise/optimize marketing spends across brands and Therapy areas – balancing push and pull mechanisms

Note: \*Differentiated generics include specialty OSDFs (controlled release, sustained release, etc.), injectables, etc.  
Source: <sup>1</sup> GlaxoSmithKline Annual Report- 2016, <sup>2</sup> Emami Annual Report, 2016, <sup>3</sup> Procter and Gamble Annual Report, 2016

# Strategy Two - Leverage Institutional Segment (will outpace retail segment)

Increase in adoption of unbranded generics in private hospitals

- Corporate hospitals are moving from branded generics to unbranded generics in order to cut cost and achieve higher margins  
*"... Corporate and chain hospitals are constantly on the lookout to reduce costs and hence, they are increasing the adoption of unbranded generics..."*

Industry Expert

Hospitals approach CMOs to manufacture unbranded generics

- Corporate hospitals are directly appointing contract manufacturers for custom made unbranded generics
- These products are labeled on hospital's name only for use by that particular hospital  
*"... Hospitals directly appoint contract manufacturers to produce unbranded generics only for the hospital. These medicines are branded in the name of hospital and only used for the hospital patients..."*

Industry Expert

Hospital specific unbranded generics provide significant savings

- Hospital specific unbranded generics provide significant cost saving to the hospital as they are procured directly from the manufacturer with minimal channel partner involvement  
*"... Hospitals get generic version of drugs, contract manufactured only for their use, reducing the cost to hospital by 75%..."*

Industry Expert

# Strategy Three - Revitalize Sales Strategy (Structure, training, performance)

	3.1 Reorganise Sales team	3.2 Re-energised Sales Training	3.3 Recast Incentive
<b>Current</b>	<ul style="list-style-type: none"> <li>Mainly structured around selling to physicians</li> <li>Medical Representatives (MRs) form bulk of the organization</li> <li>Sales representatives involved in personal order bookings</li> </ul>	<ul style="list-style-type: none"> <li>Focus on scientific training, physician engagement and management</li> <li>Limited training for communication with retailers and hospital purchase committees</li> </ul>	<ul style="list-style-type: none"> <li>Coverage and coverage frequency as per the Monthly Tour Plan (MTP) is main performance metric</li> <li>MTP consists of a list of physicians that MR is assigned to cover</li> <li>Incentive structure for MR based on targets in area of responsibility</li> </ul>
<b>Future</b>	<ul style="list-style-type: none"> <li>Re-organize/ expand the team post assessment of OTC and institutional selling dynamics</li> <li>Build capabilities for modern trade</li> </ul>	<ul style="list-style-type: none"> <li>Sharpen training on scientific selling for differentiated products and therapeutic areas</li> <li>Increase focus on sales training targeted towards retail and other channel partners</li> <li>Sharpen the training targeted towards OTC sales and institutional segment</li> </ul>	<ul style="list-style-type: none"> <li>Modify MTP to include more retailers/ stockist / channel partners / institutions</li> <li>Modify incentive structure and targets based on sales of differentiated portfolio</li> <li>Include personal order bookings in performance metrics</li> </ul>



# Strategy Four - Re-assess Manufacturing Strategy (In-house vs outsourced)

4.1 Rationalize Manufacturing Mix	4.2 Evaluate Current Outsourcing Partnerships	4.3 Modify Contract Terms of Current Partnerships	4.4 Appoint CMOs# for OTC and generics portfolio	4.5 Monitor Regulatory Developments
<ul style="list-style-type: none"> <li>Rationalize the ratio of products manufactured in-house vis-à-vis outsourced post portfolio modification</li> </ul> <p><i>"...pharma companies may have to revise their in-house vs outsourced manufacturing ratio to accommodate generics portfolio and maintain margins despite the decrease in drug prices..."</i></p> <p>- Industry expert</p>	<ul style="list-style-type: none"> <li>Evaluate the current partnerships and consider migration to outsourcing partners who have the necessary approvals</li> </ul> <p><i>"...government is going to mandate BA/BE studies and therefore, to achieve the quality of the products, pharma companies will have to appoint TPMs* complying with stringent standards..."</i></p> <p>- Industry expert</p>	<ul style="list-style-type: none"> <li>Evaluate current outsourcing partnerships and contracts to identify scope for procuring products at lower costs</li> </ul> <p><i>"...because of the rising price pressures, pharma companies need to look at their existing partnership contracts and negotiate for better margins..."</i></p> <p>- Industry expert</p>	<ul style="list-style-type: none"> <li>Evaluate CMOs for partnership to cater to portfolio additions</li> </ul> <p><i>"...if companies are adding new products such as OTC, dietary supplements and so on, they need to partner with new CMOs to cater to the new demand and achieve cost efficiencies..."</i></p> <p>- Industry expert</p>	<ul style="list-style-type: none"> <li>Closely monitor regulations impacting TPM in the pharma policy</li> </ul>

Note: \* TPM – Third Party Manufacturers, #CMO – Contract Manufacturing Organizations  
Source: Primary Research, UC Analysis

# Conclusion

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- Generics will find increasing levels of adoption in the Indian Market
- The impact of genericisation will be different for different players, depending on their size, profitability, product portfolio/ pipeline and their India footprint
- Pharma Companies, which have largely been retail focused around Branded Generics, will need to rethink their strategies
- Stringent regulations, if implemented, along with price pressure will result in a number of smaller players becoming uncompetitive and/or becoming acquisition targets
- Further, the drive to build differentiated generics capabilities will also push a number of large players to consolidate.



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