

IPA Meeting with the FDA

“Desire to Work Together”

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Washington DC
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Desire to Work Together

Outline of Presentation

- About IPA
- McKinsey View of Indian Pharmaceutical Industry
- India's Contribution to Affordable Healthcare in USA
- Partnering with the FDA
- What IPA Offers

About IPA

Indian Pharmaceutical Alliance



About IPA

Current Members (20)

- Alembic
- Alkem
- Cadila Healthcare
- Cadila Pharmaceuticals
- Cipla
- Dr Reddy's
- Glenmark
- INTAS
- IPCA
- J B Chemicals
- Lupin
- Mylan
- Micro
- Natco
- Panacea Biotech
- Sun
- Torrent
- Unichem
- USV
- Wockhardt

About IPA

Contribution

- ❑ 85% of Private Sector Spend in R&D
- ❑ 60% of Exports of Pharmaceuticals
- ❑ 43% of Domestic Sales*
- ❑ **75% of Exports to USA**
- ❑ 43 % of Total NLEM Sales*

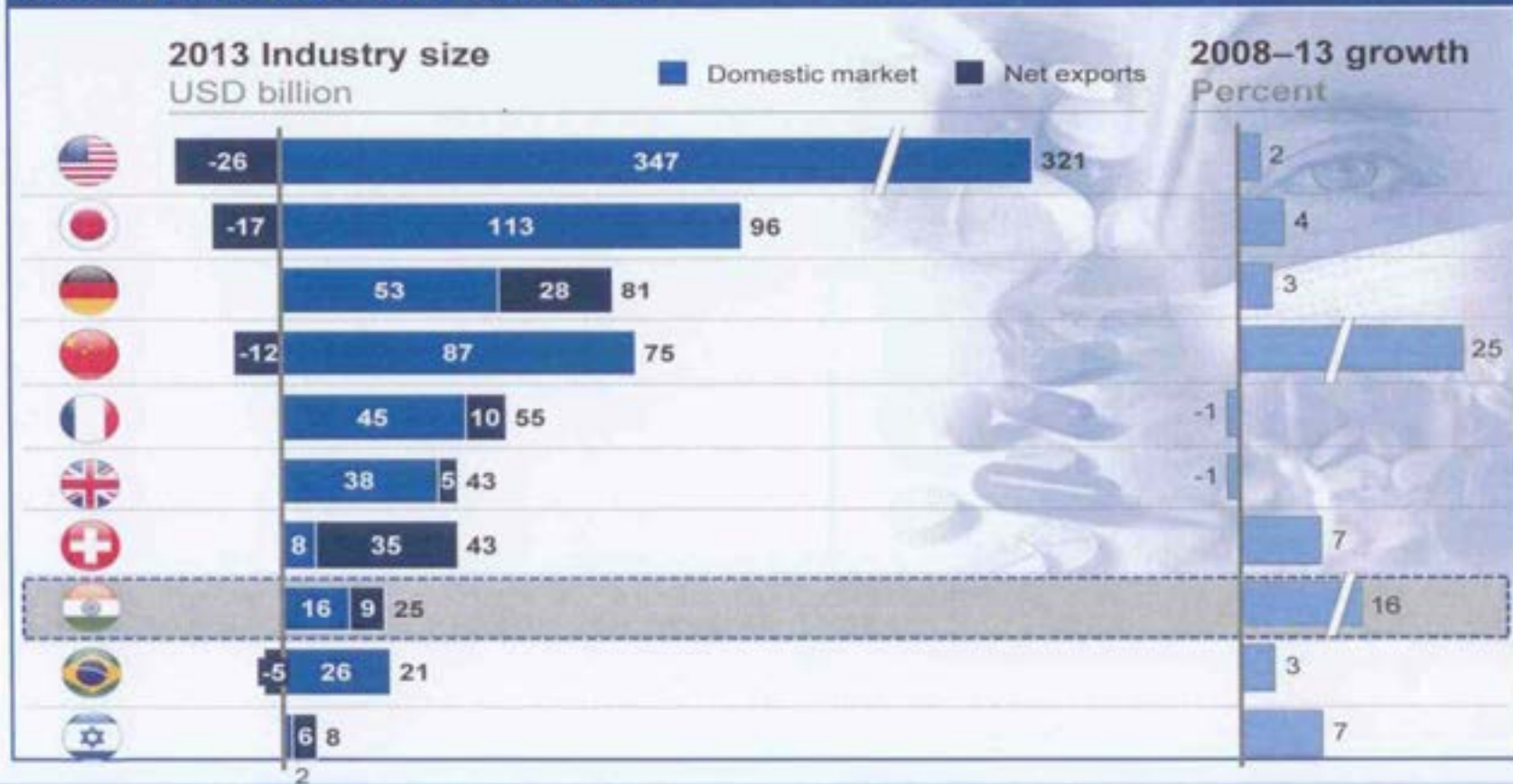
* AIOCD Pharmasoftech AWACS Pvt Ltd, MAR MAT 2014

Pharmacy of the World

McKinsey View of Indian Pharmaceutical Industry

- 1 Industry has also grown to become 8th largest country globally and continues to have one of the highest growth rates

Country wise pharma markets 2013



SOURCE: United Nations Comtrade Database DESA/UNSD, BMI, Individual country industry associations

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Courtesy: McKinsey & Co.

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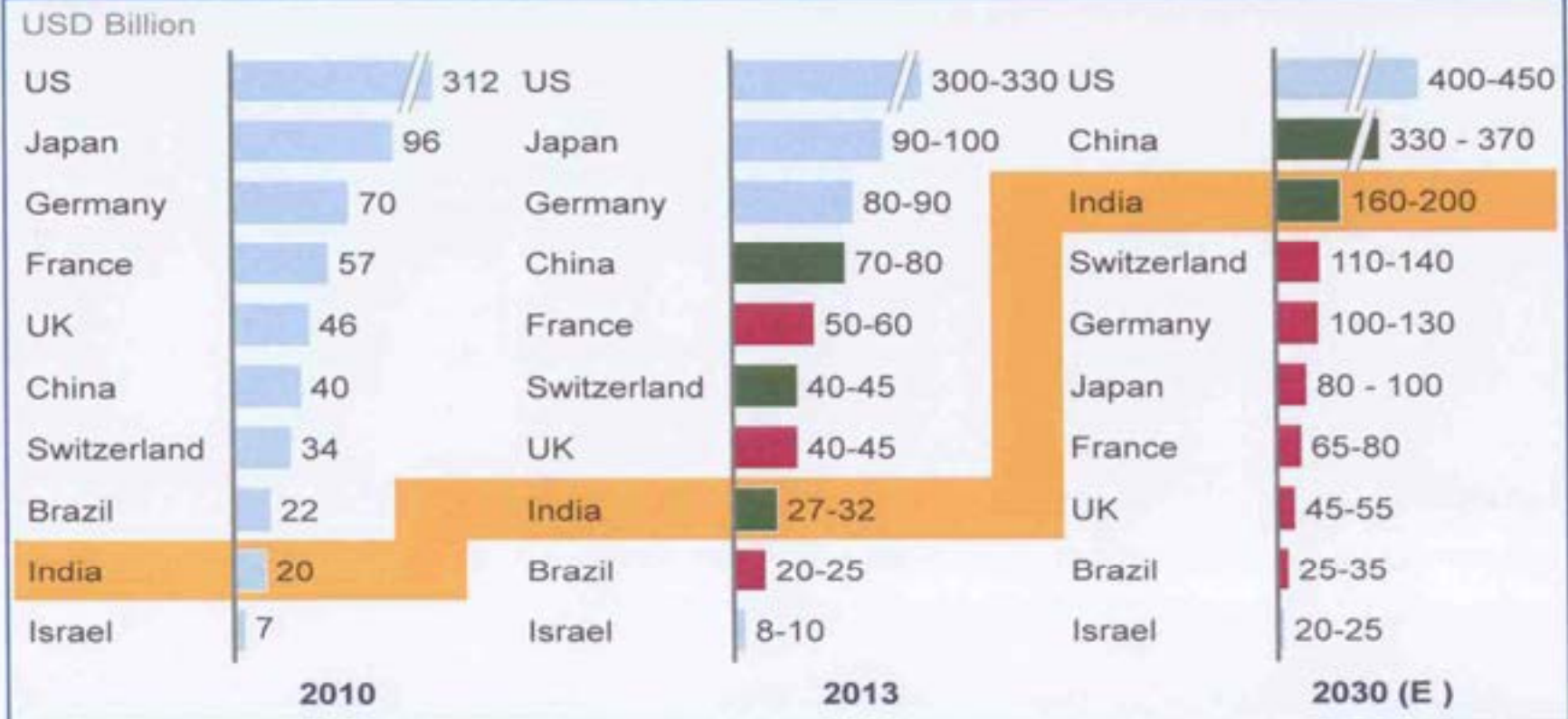
McKinsey View of Indian Pharmaceutical Industry

GLOBAL LEADERSHIP

2 Industry will also grow to become the 3rd largest globally by 2030

■ Countries improving rank ■ Countries deteriorating rank

Comparison of top 10 global pharma markets¹ between 2010-2030

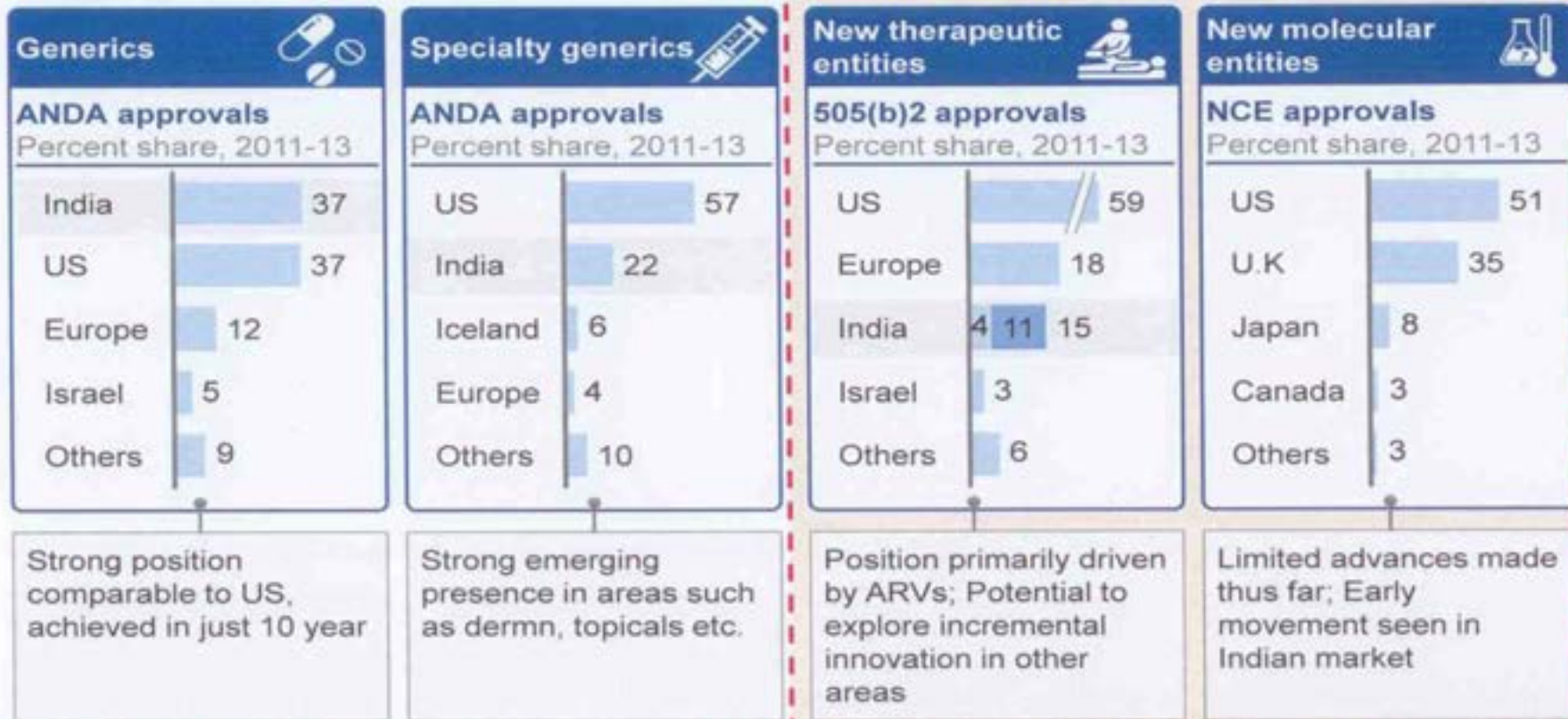


¹ Pharma market defined as Domestic Consumption + Exports - Imports
SOURCE: UN Comtrade, BMI, Local industry association data, team analysis

McKinsey View of Indian Pharmaceutical Industry

5b However, India currently has nascent position in these innovation spaces

■ ARV Combinations



Strong position comparable to US, achieved in just 10 year

Strong emerging presence in areas such as dermn, topicals etc.

Position primarily driven by ARVs; Potential to explore incremental innovation in other areas

Limited advances made thus far; Early movement seen in Indian market

SOURCE: Evaluate, FDA, Robert W Baird & Co survey data

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Courtesy: McKinsey & Co.

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India's Contribution to Affordable Healthcare in USA

ANDA Filing Run-Rate of Six Leading Indian Companies

Company	FY10	FY11	FY12	FY13	FY14	H1FY15
Dr Reddy's	14	7	17	19	13	11
Sun Pharma	30	28	22	13	29	15
Lupin	37	21	25	21	20	8
Glenmark	13	13	12	18	20	11
Cadila	14	24	21	25	50	23
Aurobindo	13	24	30	34	78	42
Total	121	117	127	130	210	110

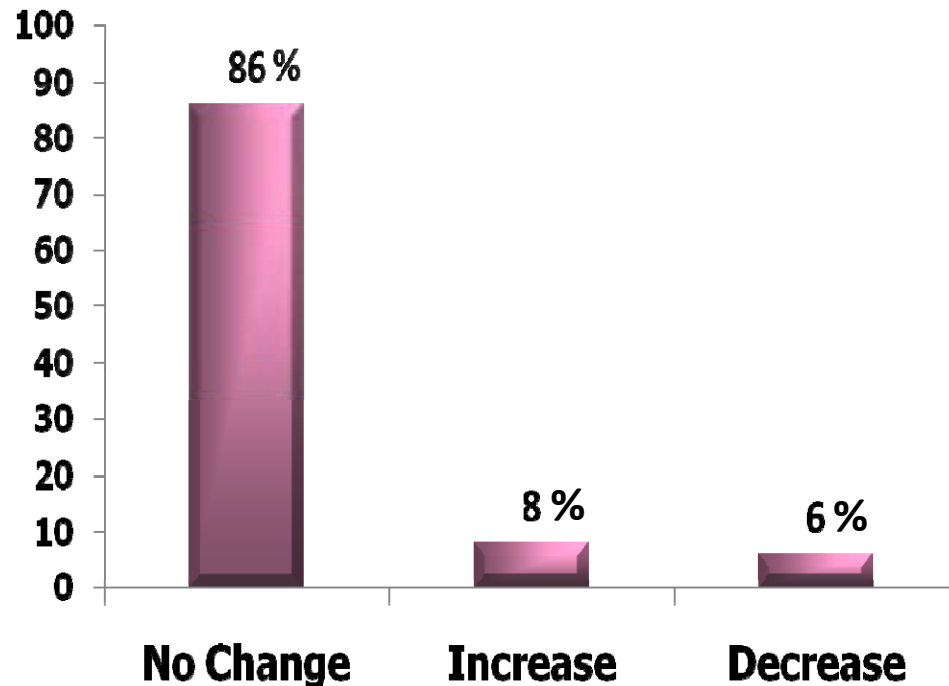
Source: Company Reports / J P Morgan

India Files Over 40% of Total Generic Applications

India's Contribution to Affordable Healthcare in USA

Price Changes in 2014 Over 2013

Illustrative Sample of 582 Products of Six Leading Indian Companies



Company	Products Evaluated	No. of Products		
		No Change	Increase	Decrease
Lupin	71	53	5	13
Dr Reddy's	101	75	16	10
Ranbaxy	97	84	9	4
Sun Pharma	143	136	3	4
Aurobindo	108	100	5	3
Cadila	62	54	7	1
Total - Nos	582	502	45	35
Total - %	100	86	8	6

Source: Morgan Stanley

Partnering with the FDA

Objectives

- ❑ Strengthen India's CDSCO
- ❑ Provide an Effective Interface with Government
- ❑ Promote Capacity Building
 - Industry
 - Academia
 - CDSCO
- ❑ Identify and Resolve Cultural Issues
- ❑ Quick Resolution of Quality Issues

Partnering with the FDA

Strengthen India's CDSCO

- Initiate Structural Changes
- Empower and Elevate Position of DCGI
- Insist on Transparency & Accountability
- Push for PICs Membership
- Define Pathway & Milestones

Partnering with the FDA

An Effective Interface with Government

- ❑ India – A Complex Country
- ❑ Multiple Ministries/Departments Overseeing Pharmaceuticals
- ❑ IPA Can Be an Effective Vehicle to Deal with Multiple Government Agencies

Partnering with the FDA

Capacity Building

- Explains Science Behind the Rules
- Modifying Pharmacy Curriculum for Appropriate Skills
- Exposure of Academia to FDA
- Training of Drug Control Officers/Inspectors

Impact of May 2014 Workshops

Effective Quality Systems

Hyderabad

Goa

Ahmedabad

Chandigarh

FDA/CDSCO/IPA Workshops – May 2014

Effective Quality Systems

Courtesy FDA

Opening Remarks : Dr Leslie Ball, Assistant Commissioner & Deputy Director
Office of International Program

Key Note Address : Mr Howard Sklamberg, Deputy Commissioner
US FDA Global Regulatory Operations and Policy

Faculty : Dr Albinus D'Sa, Acting Country Director
US FDA India Office

Alicia Mozzachio, Branch Chief
US FDA Center for Drug Evaluation and Research

Thomas Arista, Drug Program National Expert
US FDA Office of Regulatory Affairs

Farhana Khan, International Program & Policy Analyst
US FDA India Office

FDA/CDSCO/IPA Workshops – May 2014

Effective Quality Systems

Topics Covered

- An Overview of 21 CFR 210/211
- An Overview of ICH Q₇ for Active Pharmaceutical Ingredients
- The Roles and Responsibilities of the Quality Control Unit
- An Overview of Personnel Qualifications and Responsibilities
- An Overview of Records and Reports
- OOS, Complaints and Failure Investigations
- An Overview of Process Validation
- An Overview of Data for Manual and Automated Systems and Electronic Records

FDA/CDSCO/IPA Workshops – May 2014

Effective Quality Systems

Summary of Evaluation for Eight Sessions Faculty & Content

Location	Fair	Good	Excellent
Hyderabad	25	406	295
Goa	39	331	350
Ahmedabad	19	256	346
Chandigarh	23	275	334
Total – Nos.	106	1,268	1,325
Total %	4	47	49

Over 96 % of Participants Rated Good/Excellent

FDA/CDSCO/IPA Workshops – May 2014

Effective Quality Systems

Satisfaction Level

Location	No. of Forms Received	No Response	Yes	No	Partially
Hyderabad	93	5	66	0	22
Goa	90	0	59	1	30
Ahmedabad	81	4	64	0	13
Chandigarh	79	0	60	2	17
Total	343	9	249	3	82
%	100	3	72	1	24

72% of Participant Achieved their Objective

FDA/CDSCO/IPA Workshops – May 2014

Effective Quality Systems

Overall Rating

Location	Not Rated	Poor	Average	Good	V. Good	Excellent
Hyderabad	2	1	2	20	54	14
Goa	0	0	6	25	37	22
Ahmedabad	10	0	0	5	35	31
Chandigarh	0	0	3	26	28	22
Total	12	1	11	76	154	89
%	4	0	3	22	45	26

93% of Participants Rated "Good to Excellent"

Partnering with the FDA

Cultural Issues

- ❑ Barriers to Effective Communication
 - Fear
 - American English
 - Accent
- ❑ Attitudinal Diversity

An Effective Vehicle to Address These Issues

Partnering with the FDA

Quick Resolution of Quality Issues

An Appropriate Mechanism
for
Dialogue Between the Inspected Company and the FDA
to
Provide a Process Similar to One Followed by the
District Offices in the USA

What IPA Offers

India Enjoys a Unique Position

- ❑ Benefits of Higher Regulatory Scrutiny
- ❑ Incorporates Diverse Requirements of All Major Agencies
- ❑ Drives Access and Affordability Across the World
- ❑ Services Markets of More than 200 Countries
- ❑ Offers, Quality, Competition & Stability of Prices

What IPA Offers

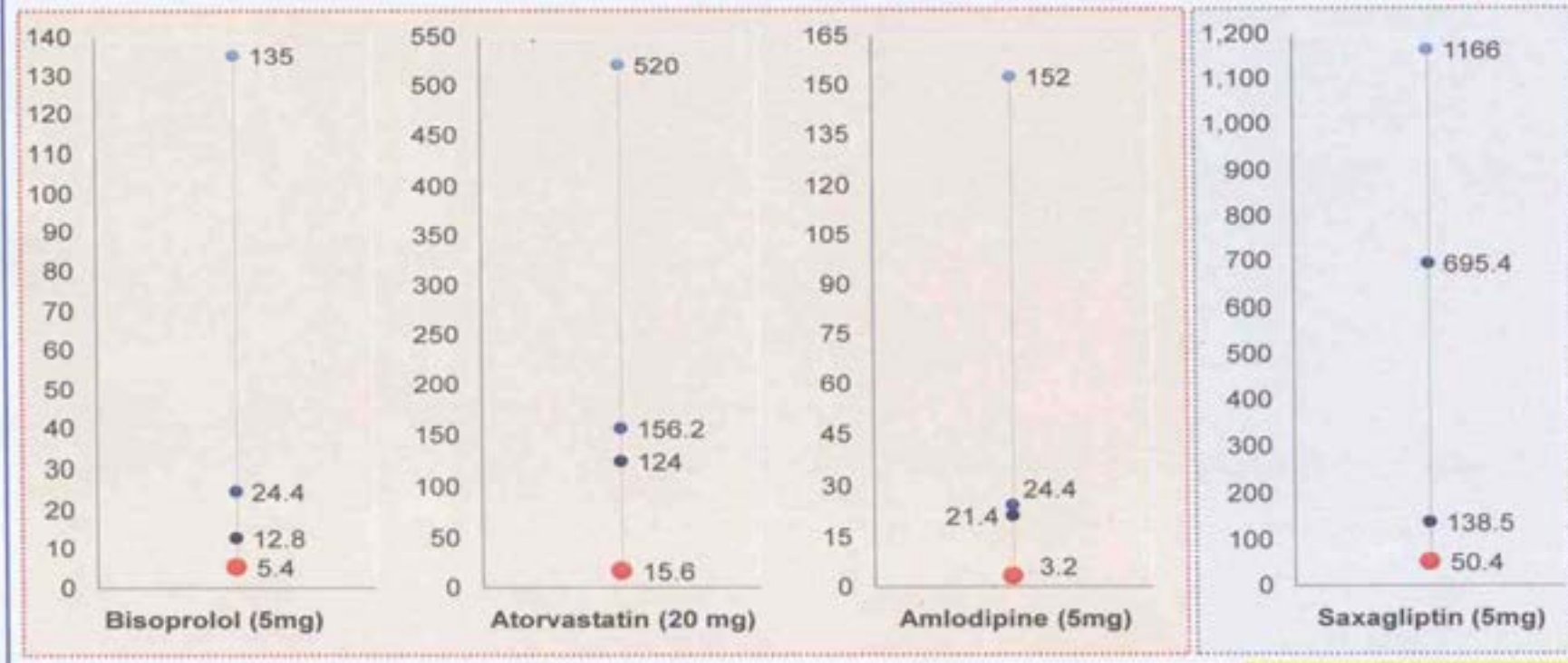
3a Beyond growth, Indian industry has also made significant contribution to driving access, affordability both in India..

ILLUSTRATIVE

India continues to drive affordability through low priced¹ drugs across markets

US cents per pill

Gx Patented US Germany China India



Need to validate data

¹ Average price across brands

SOURCE: Lauer-Taxe (Germany), PriceRx (US), GBI Pharma (China), AIOCD (India), Indiamedline, team analysis

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Courtesy: McKinsey & Co.

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What IPA Offers

3b

... as well globally – Example of essential medications in developing markets

60%+ of global vaccine production



Annual UNICEF supply globally

30%

60%+ of global supply of ARV drugs



Annual UN purchases

60-80%



SOURCE: Press Information Bureau by Govt, "Indian Vaccine market report 2013"

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Courtesy: McKinsey & Co.

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THANK YOU

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