

Presentation On Pharmaceutical Sector in India



**by
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**Mumbai
30 May 2019**

Indian Pharmaceutical Alliance

Outline of Presentation

- ❑ Indian Pharmaceutical Industry
- ❑ Importance of Europe
- ❑ Possible Opportunities and Threats with Brexit

Indian Pharmaceutical Industry

Pharmacy of the World

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 Gol, "Indian Vaccine market report 2013"

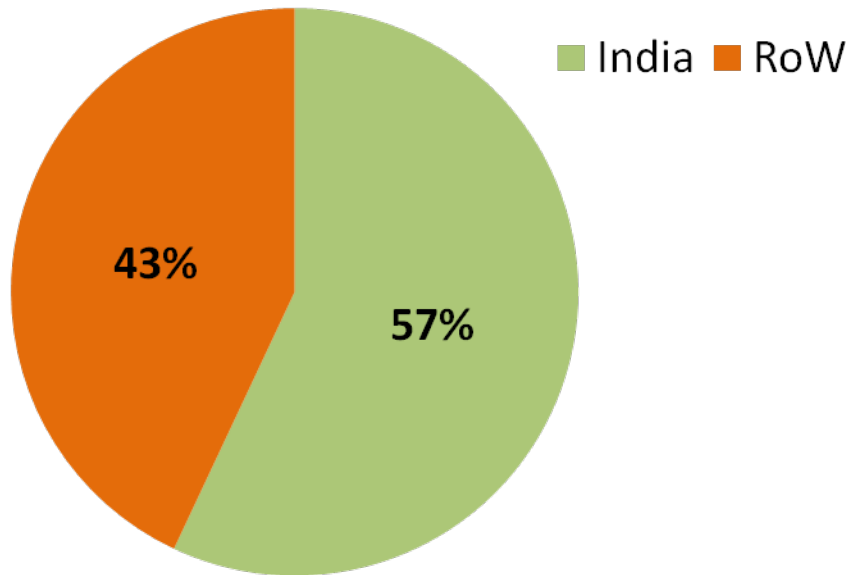
McKinsey & Company | 10

Indian Pharmaceutical Industry

Contribution to WHO PQ

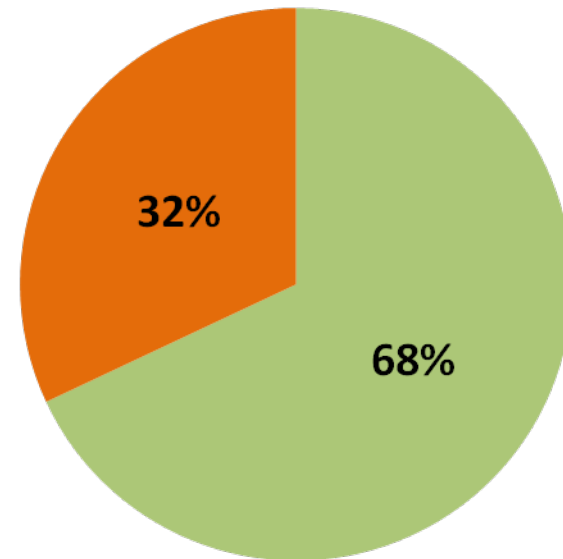
APIs

On PQ List



70 Out of 123

Under Assessment



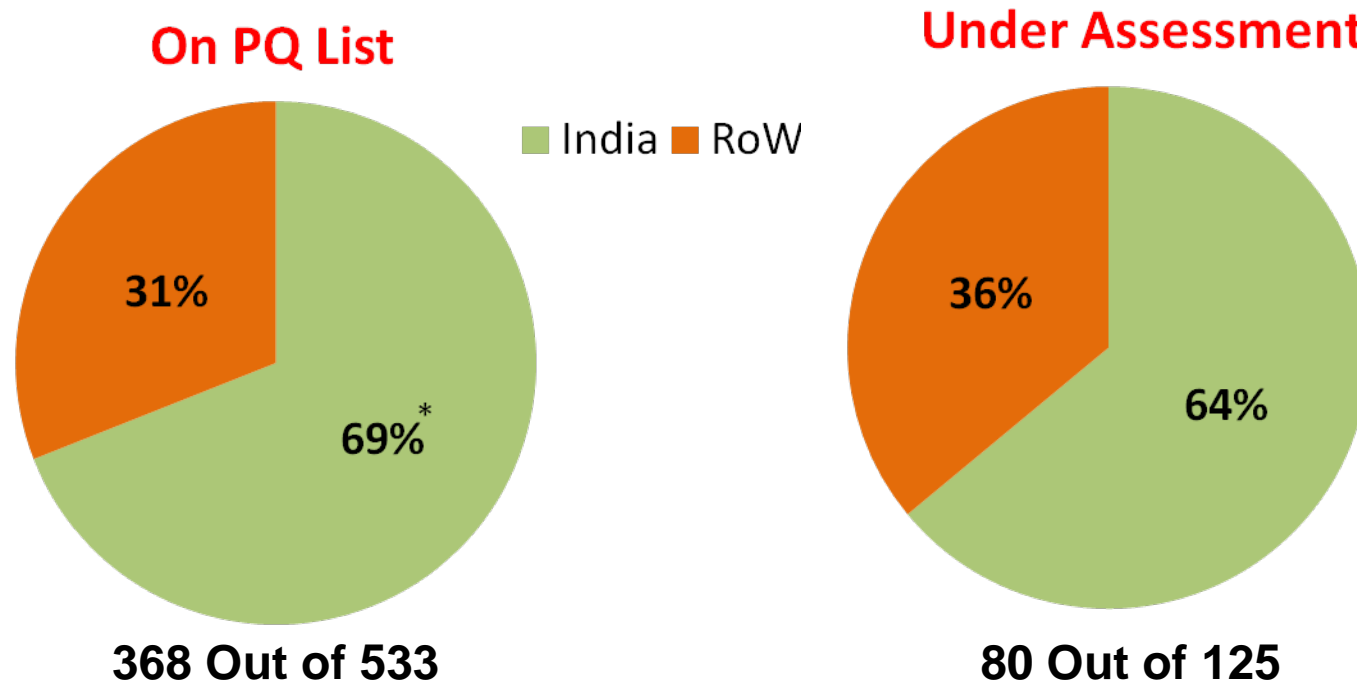
30 Out of 44

Courtesy: Presentation by Vimal Sachdeva, WHO

Indian Pharmaceutical Industry

Contribution to WHO PQ

FPPs



* Includes those that are listed based on alternative listing route.
Number of Prequalified by WHO Under Full or SRA Route:
270 out of 427=63%

IPA Initiative

Towards Excellence in Quality 1/4



Be the conduit of change through thought leadership, knowledge development, and best practice sharing

Measure, benchmark, and publicise the achievements of the Indian Pharma Industry in Quality

Expand the size and base of Quality talent in India

Deepen, and strengthen the industry's relationship with key stakeholders – both within and outside India

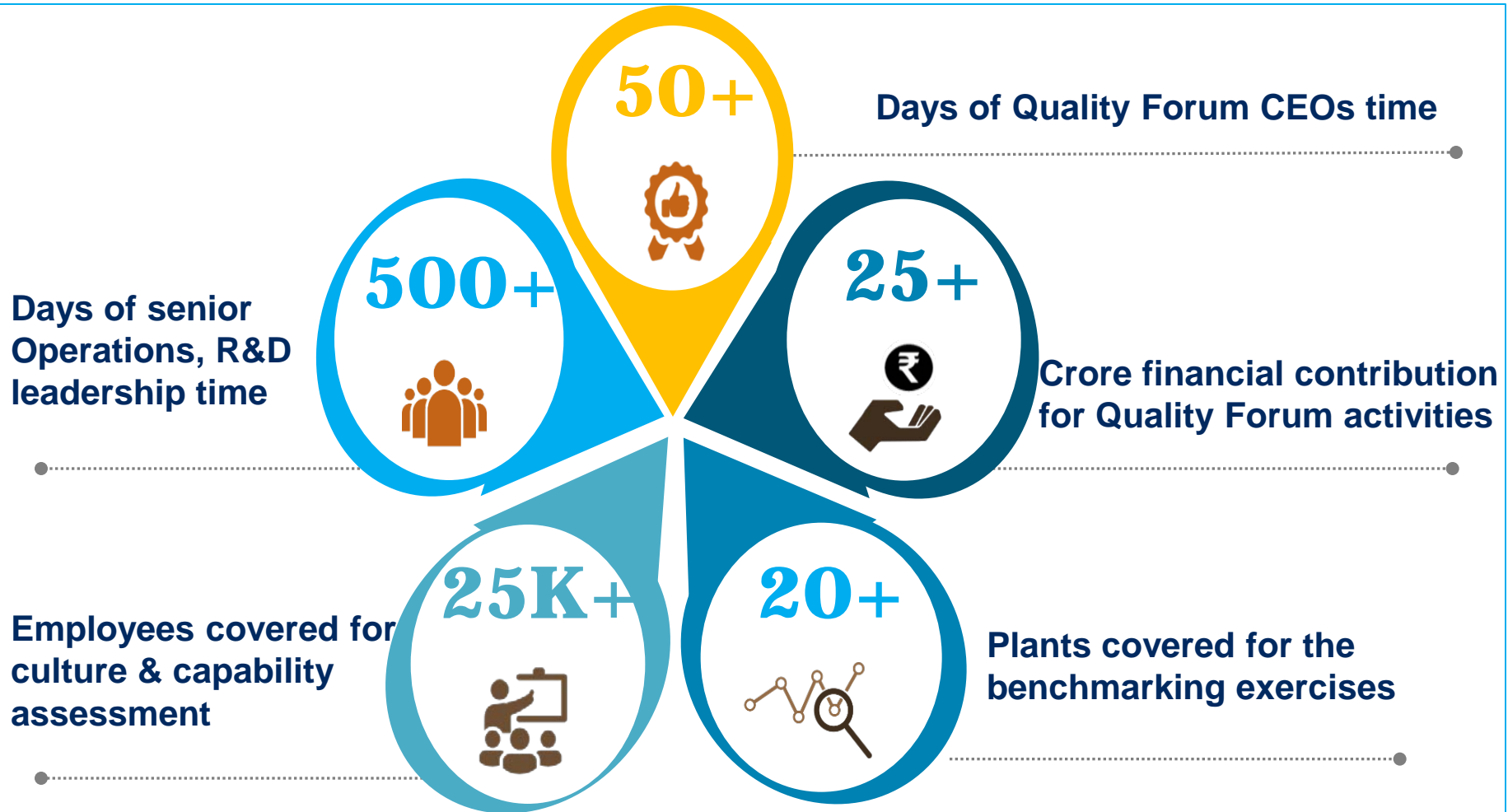
Provide platforms for members and other stakeholders to interact and network

IPA QF Mission

The IPA Quality forum was setup 3 years back, by a group of 6 founding member companies, and supported by McKinsey & Company as their knowledge partner

Opportunities and Threats with EMA

Towards Excellence in Quality 3/4



Dedicated McKinsey Team working with IPA QF for the last 2.5 years

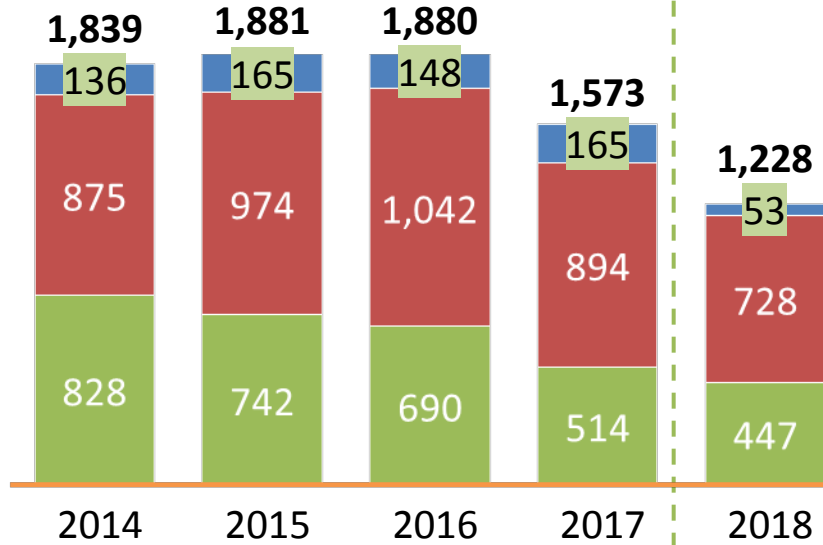
The Industry has continued to show progress- Inspection outcomes in India have improved and are now more in line with global outcomes

Towards Excellence in Quality 2/4

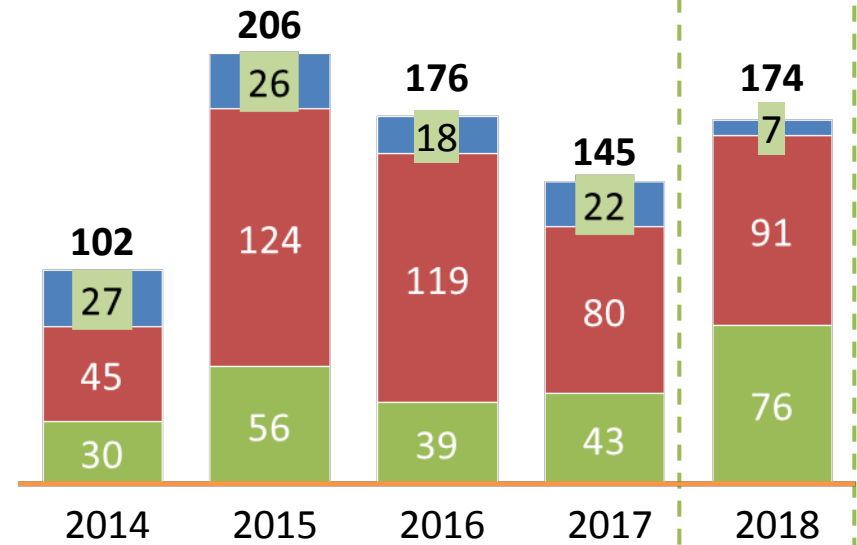
Outcomes of inspections¹

■ OAI ■ VAI ■ NAI

Global



India



Indian inspections as a share of global

6%

11%

9%

9%

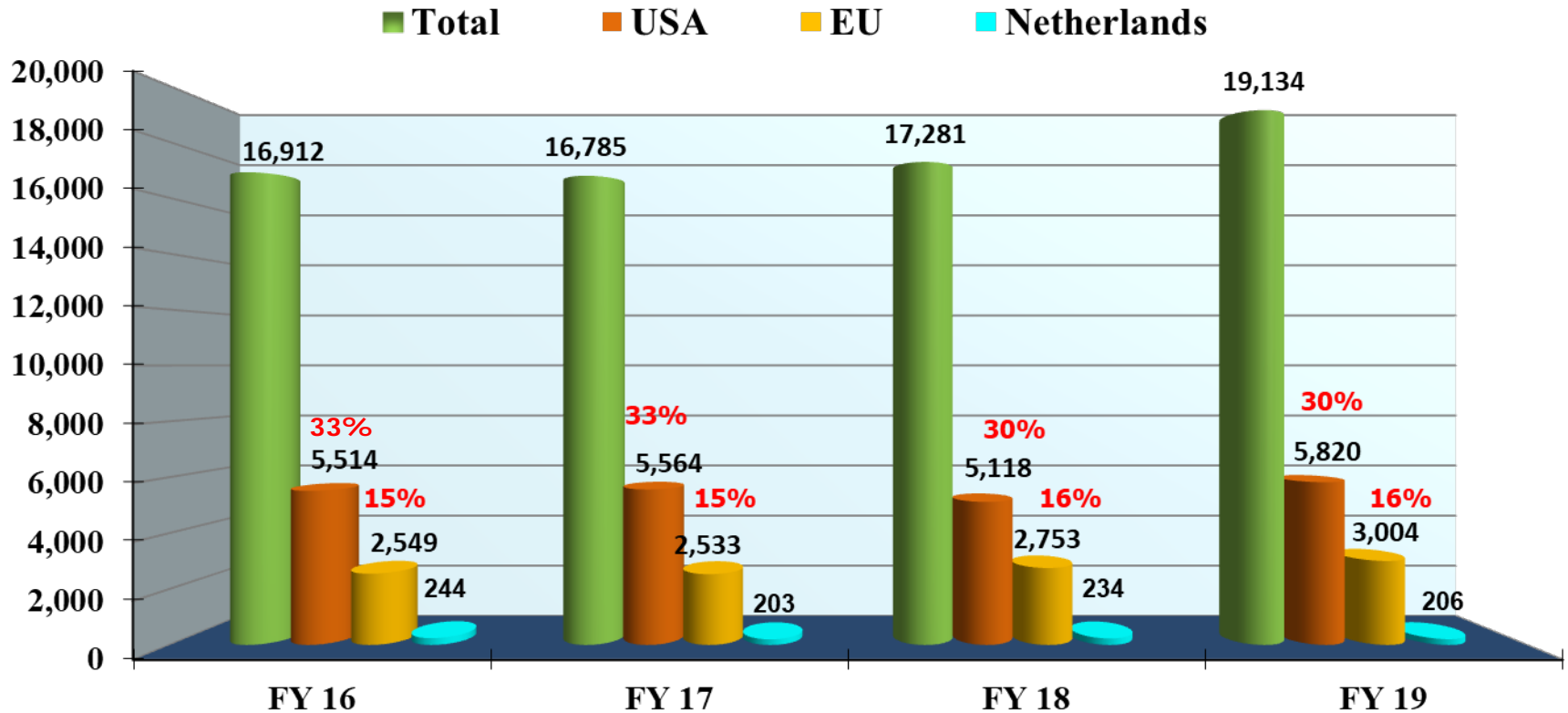
14%

FDA inspection data for CDER and Drug Quality Assurance projects, for Jan – Dec cycle (February 25, 2019)

¹ Data from Jan – Dec cycle

Indian Pharmaceutical Industry

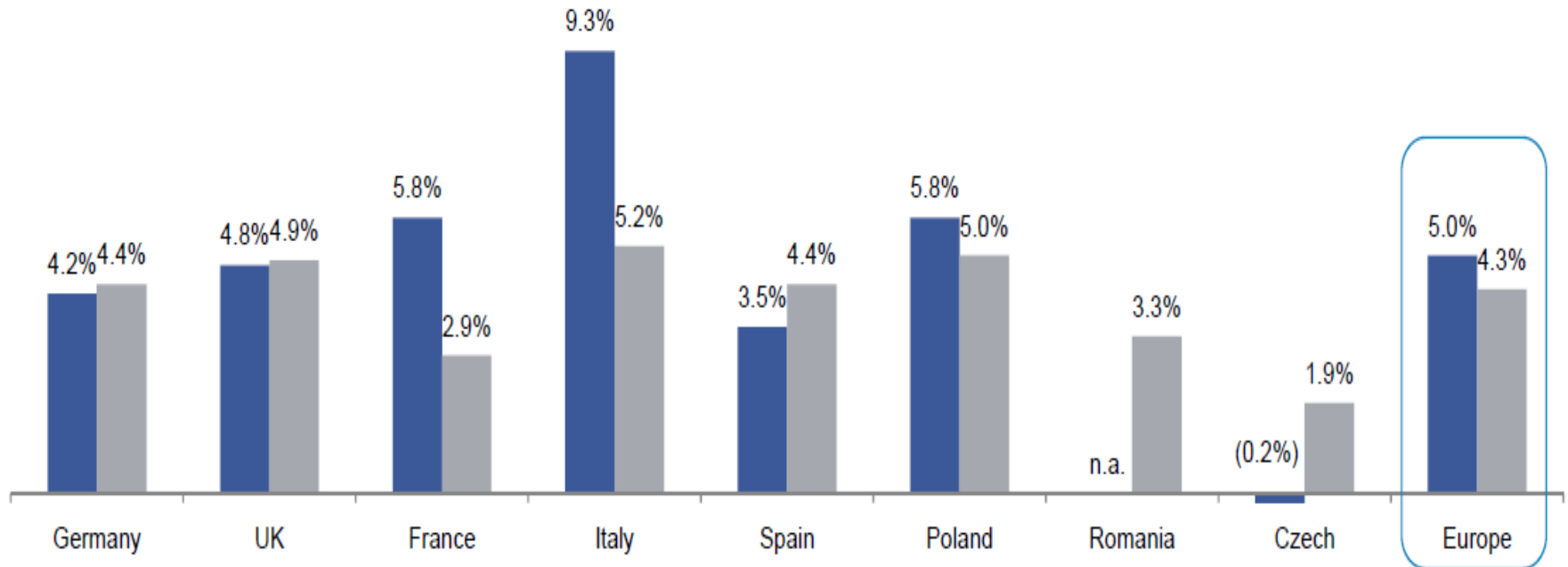
India's Exports of Pharmaceuticals (Mn USD)



Source : Pharmexcil Data Handbook

Opportunities: European Market is Growing at Healthy Rate

Forecast for Major Markets : IMS '16-'21 vs. BCG '17-'22 Gross sales CAGR (% p.a.) ⁽²⁾



Market Size: € - FY 2016

■ IMS Prognosis ■ BCG Market Model

6.4

5.0

4.1

3.4

2.6

1.7

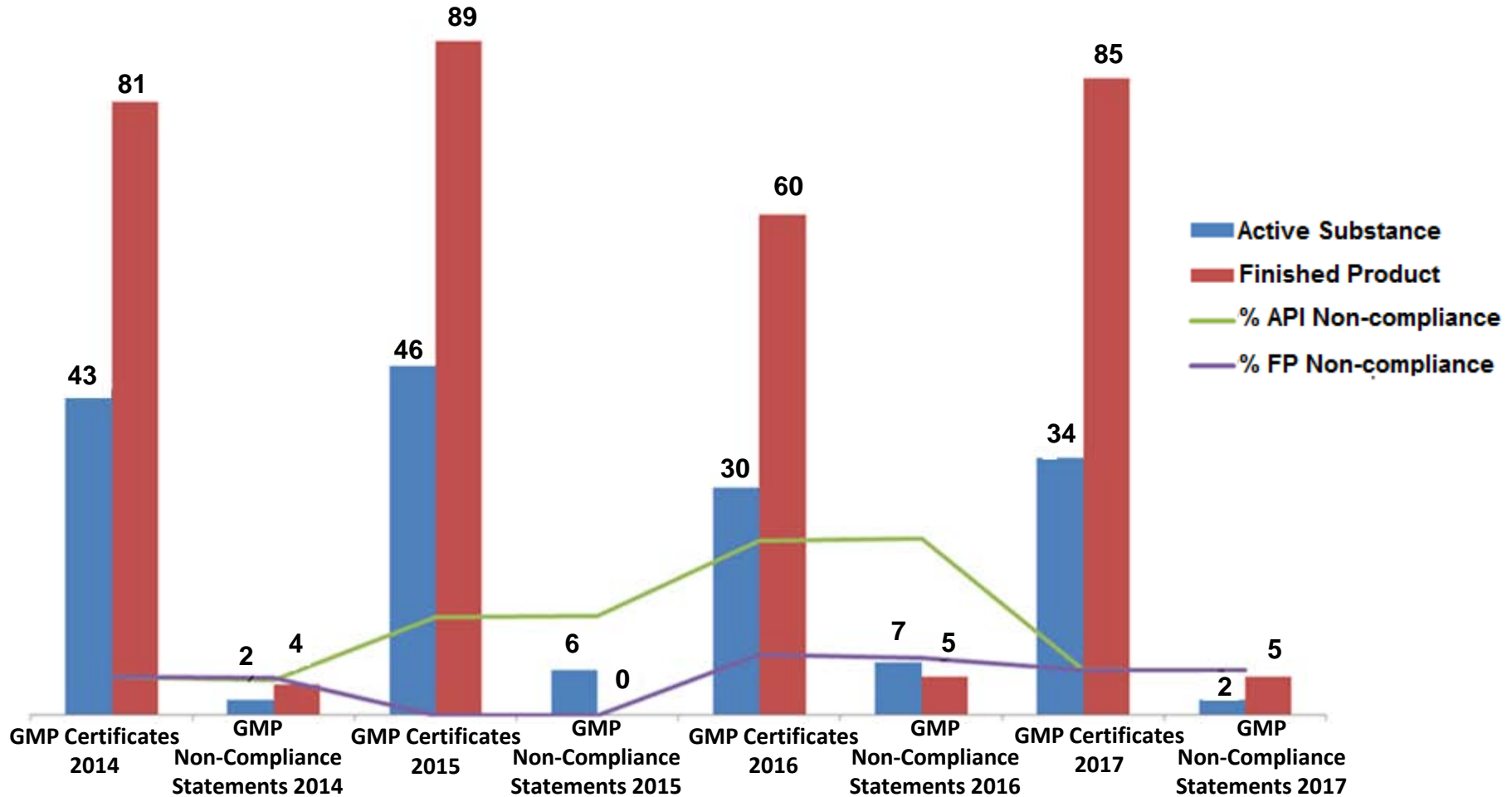
0.6

0.5

29.4

Opportunities and Threats with EMA

GMP Inspections Performed by EU Inspectorates in India: 2014-17



Source: EudraGMDP data 9th January 2018

Courtesy: Presentation by Andrei Spinei, EMA

Opportunities in EU Market

- Ageing population with a rise in prevalence of chronic and other diseases (e.g. cancer)
- Increased acceptance among consumers, physicians and pharmacists of generics as equivalent of branded pharmaceuticals
- increasing pharmaceuticals spending
- Ongoing cost-containment measures and increasing pressure from expensive innovative treatments

Business Landscape

- Uncertainty arising out of Brexit : Next steps?
 - Who will take over supervision of the manufacturing sites of medicinal products in third countries previously supervised by UK authorities?
 - What happens to manufacturing site for which the Union GMP certificate has been issued by UK authorities
- 28 countries, each country with its own nuance; with Brexit complications may increase
- Different regulatory procedures and timelines
- Different patent landscapes
- Multiple SKUs and small volumes

Indian Pharma industry: Going forward

- Large Indian Companies are best suited to deal with market complexities of EU
- Product portfolio and customised approach will help in leveraging the opportunity
- Brexit and aftermath will be key area to decide the way forward
- EU is high priority market for many Indian companies

THANK YOU

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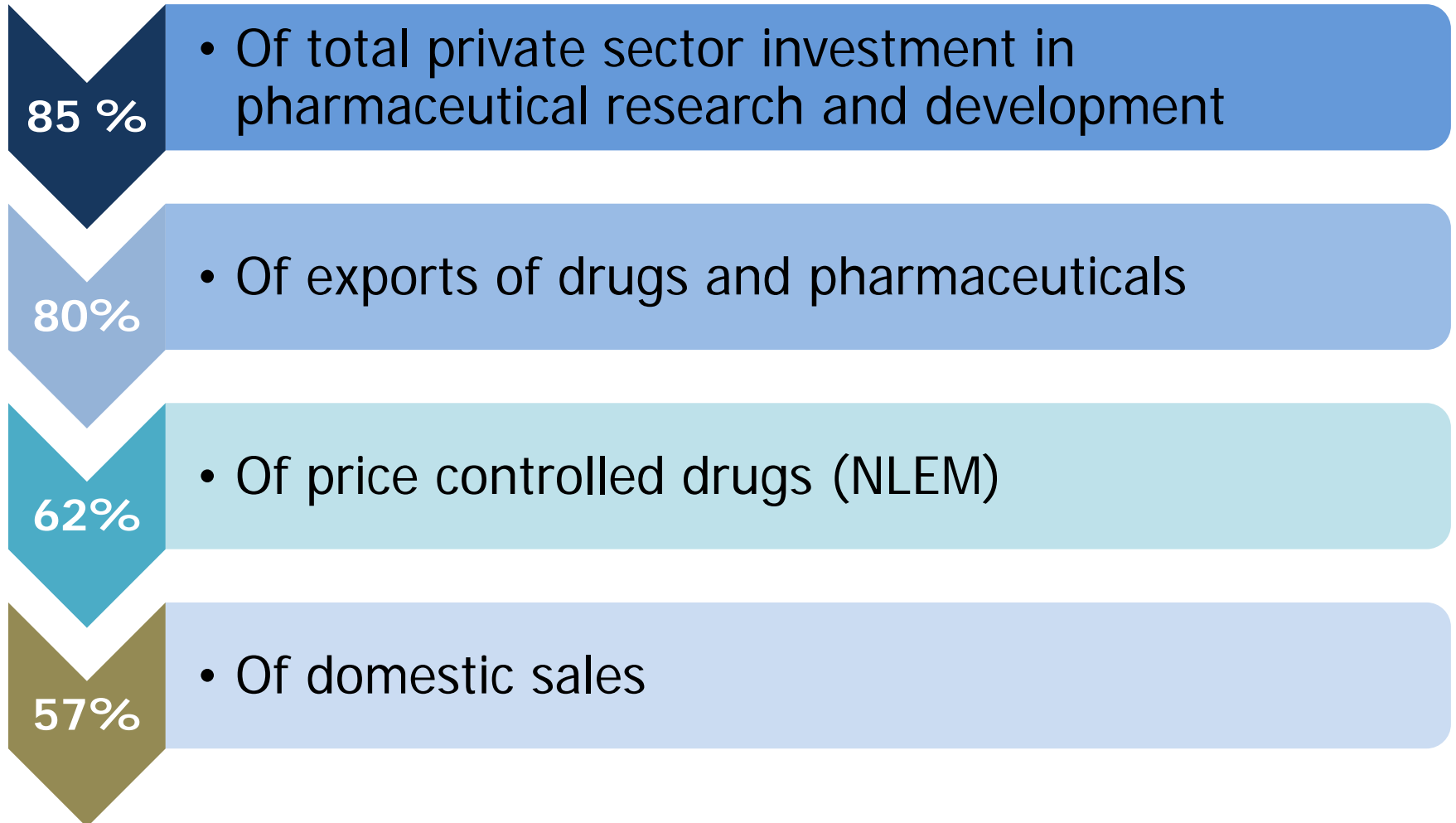
Indian Pharmaceutical Alliance

Current Members (23)

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

Indian Pharmaceutical Alliance

Contribution



* IQVIA MAT Mar 2019