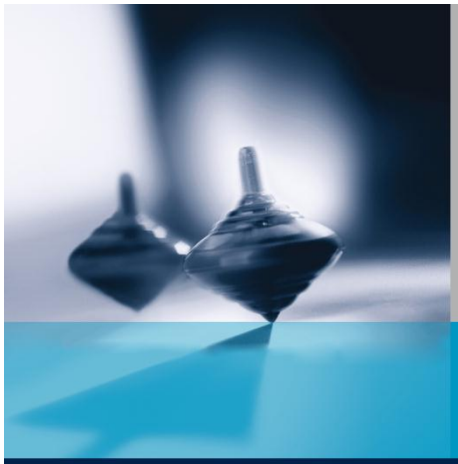


ESB BUSINESS SCHOOL
REUTLINGEN UNIVERSITY

heads the EU funded
Centre for European Business Studies
(CEBS) at the S.P. Jain Institute of
Management & Research in Mumbai

CEBS
CENTRE FOR EUROPEAN BUSINESS STUDIES
REUTLINGEN - MUMBAI

Mannheim, August 2012

Drug Supply 2.0

How to manage a disaggregated Pharmaceutical Supply Chain

Ulrich Korneck
Michael Jarosch
Prof. Dr. Harald Augustin (ESB Business School)

Value Chain Excellence. Strategy to Results.

CAMELOT
Management Consultants

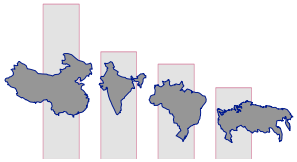
Collaborative study by ESB Business School and Camelot Management Consultants on the rising impact of 3rd Party Suppliers

Pharmaceutical companies are seeking new ways to operate due to:

Background

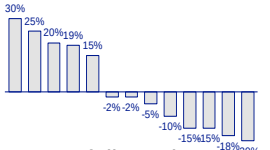
- Increasing governmental influence and new payer models lead to reduced margins even with protected portfolios.

- The shift of sales growth to emerging markets (Pharmerging 17):
  While established markets show a one digit growth BRIC is expected to grow by more than 13 %.



BRIC Sales Growth

- Rising complexity in R&D leads to a gap in the pipeline of new entities. Some companies struggle to replace the sales expiring and are forced to assess their cost structure.



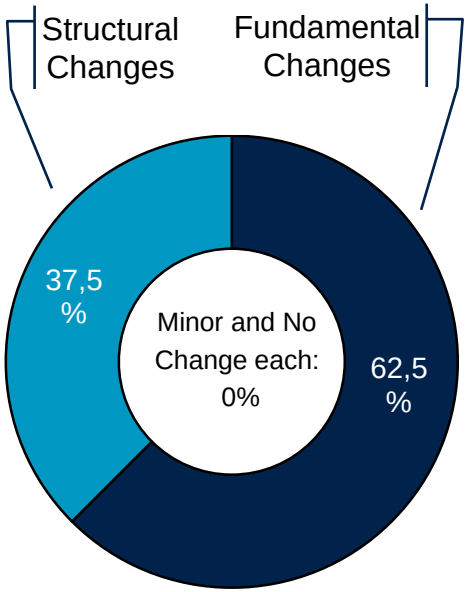
Net portfolio replacement

Aim and Method

Identify the changes to be made within the pharmaceutical value chain to operate at lower costs, maintain revenues and serve new markets.

Camelot Management Consultants and the ESB Business School contacted 28 of global top 50 Pharmaceuticals for structured interviews.

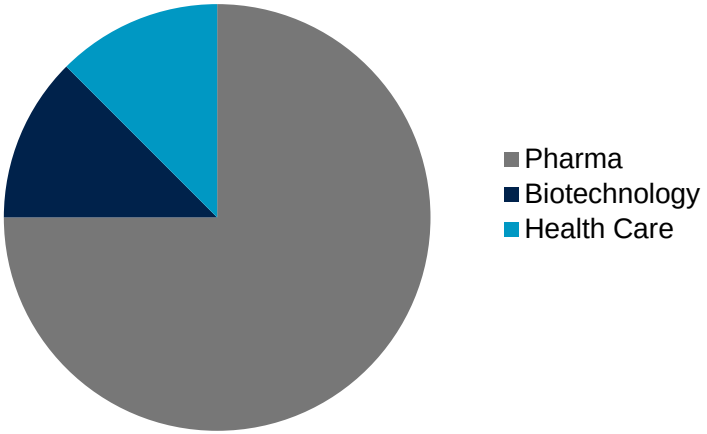
Q: Will the pharmaceutical supply chain face changes due to the outsourcing activities?



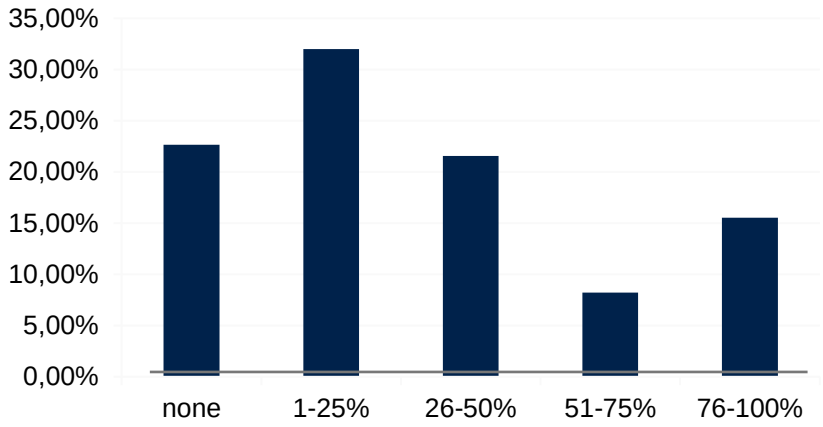
The participants base is focused on Pharma including Biotech showing a cross section of big and mid sized Corporations.

Participant overview

Sectors of participating companies



Degree of outsourced functions



Country of origin: Headquartered within the industrialized markets (US, EU & Japan)

Geographical Scope: All interviewed companies are active on the world market

Average # of employees: 57.008 Full Time Equivalent

Source: Camelot Analysis

Executive Summary (1/2)

1 The rise of Pharmerging markets is leading to a fundamental change in the way the supply chain operates

- Pharmaceuticals concentrating on their core competence to reduce costs.
- Manufacturing and distribution of solid forms are considered to have the highest potential for low-cost production.
- Over 50 % of production volume is dedicated to third party manufacturing.
- The expected cost reduction is on average 19%.

2 Responsibility of third party management shifts from manufacturing towards supply chain management

- While influence of manufacturing departments is decreasing, the supply chain is expected to take on the role of the integrator within the supply network.
- Cost and delivery reliability are the main drivers for outsourcing.
- Collaboration in terms of planning, process improvement and quality management are considered to become part of the supply chain responsibilities.

3 The management of a third party network differs completely from managing own sites.

- Almost all Pharmaceuticals intend to manage their external supply network by objectives as in an own network.
- The contractual basis for management by objectives is mostly a regular KPI measurement.
- Only one in ten Pharmaceuticals already implemented a KPI system with their key service suppliers.
- Only a single participant has already built up a formal life cycle management for their third party suppliers.

Executive Summary (2/2)

4

Development of advanced information exchange

- All participants (97%) plan to share more information to collaboratively reduce interface costs.
- Mutually collaborative planning and replenishment are desired.

5

Supply security, quality and costs are the main drivers for evaluating the CMOs

- 75 % will apply KPIs concerning the supply security such as adherence to delivery terms or adherence to schedule.
- 72 % will apply KPIs concerning the costs such as the revised price, the offer price or the total cost of ownership.
- 62 % will apply KPIs concerning the quality such as classical quality KPIs, handling or compliance.
- Less than 50 % will apply KPIs concerning service and innovation.

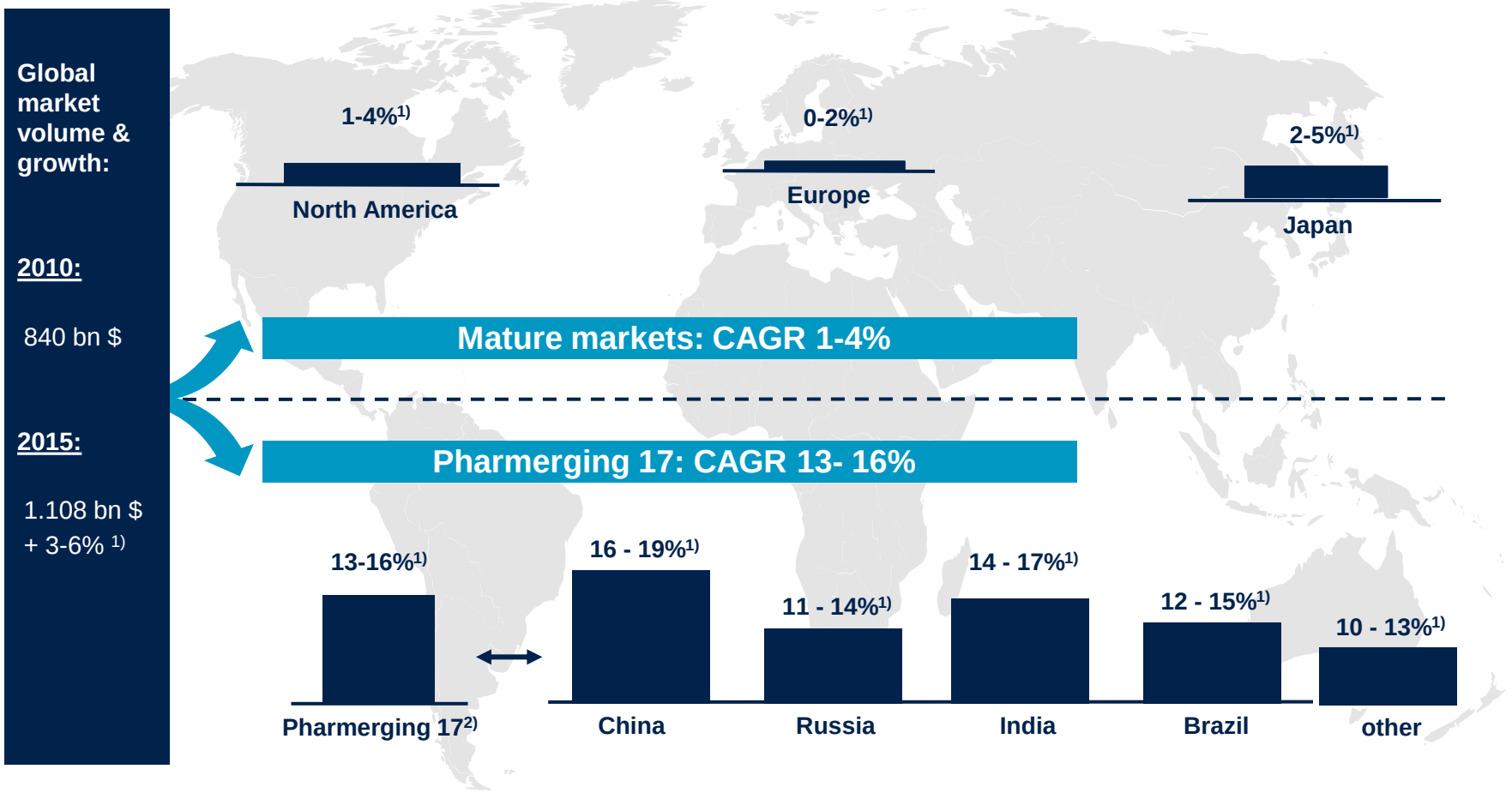
6

Multi/Dual - sourcing is the preferred concept for supply security to avoid contract penalties and shortfalls

- Within the next years the pharmaceutical industry will establish more safety concepts (especially dual sourcing) resulting in termination of conventional contract penalties.
- 67 % of the interviewed companies will shift inventory ownership towards their CMOs.

Pharmaceutical sales

Market sizes and growth rates 2009 – 2015[1)] in billion US $



Notes: 1) CAGR constant USD
2) China, Brazil, Russia, India, Venezuela, Poland, Argentina, Turkey, Mexico, Vietnam, South Africa, Thailand, Indonesia, Romania, Egypt, Pakistan, Ukraine
Source: IMS Health Market Prognosis September 2011

The current trends in the pharmaceutical industry create a strong necessity to act in order to secure mid-term success

Exceptional growth in Pharmerging 17

- Classic markets USA, Europe and Asia with increasing price pressure due to **health care reforms**
- Pharmerging markets chance to **grow up to 15%**[3)]
- Lower per capita spending demands lower price products - **increasing pressure on COGS** when entering these markets
- Increasing **import regulations** by Pharmerging 17 force direct investments or collaborations
- Greenfield investment to serve Pharmerging 17 markets locally are **risky and unlikely** due to low cost structure

Hurdles to maintain revenue & margins

- Only **marginal new Phase III entities pipeline**
- Most innovators deriving 44% of portfolio sales by **top 3 mature products**[1)]
- **Patent expiry** in combination with generic competition endangers sales worth $100b in the period from 2009 to 2015
- **Termination of Phase III Innovations** doubled between 2004 and 2009[1)]
- Biotech innovators struggle for funding (due to **reduced innovation rate**[2)4)])
- **R&D Cooperation** with in-licensing of development candidates
- Generics manufacturers **use the low labor costs in India and China** and increase the price pressure

Shift in market

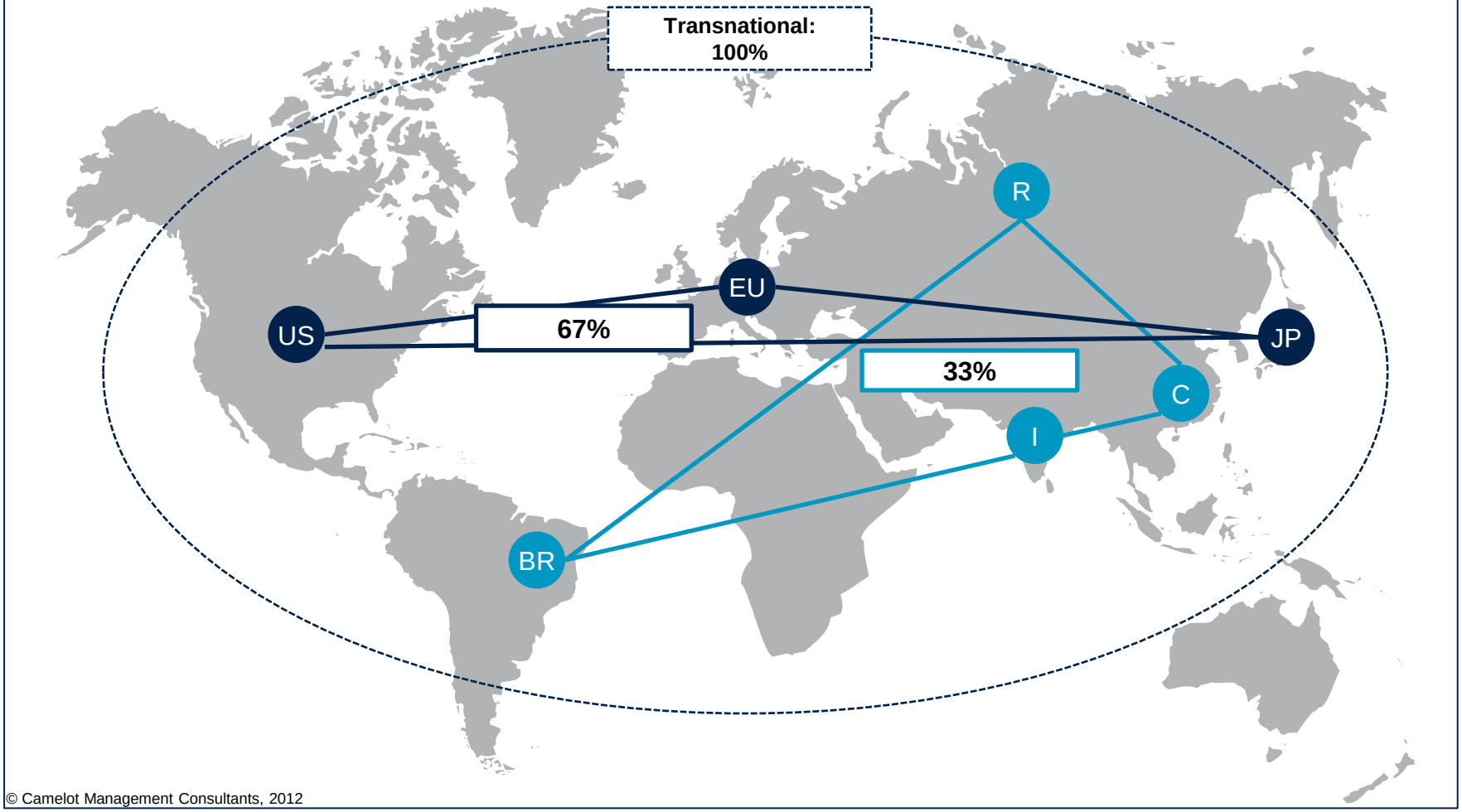
Increasing cost pressure

Established pharmaceutical companies must reshape their value chain!

Notes: 1) CMR 2010 Pharm. R&D Factbook 2) IMS Health biotech update 2007 3) Helvea 2010 “Off to new horizon” 4) the FDA approved just 17 new molecular entities and 2 biologic license applications in 2007, the lowest number recorded since 1983 (WorldBusinessResearch 2010); Camelot Analysis;

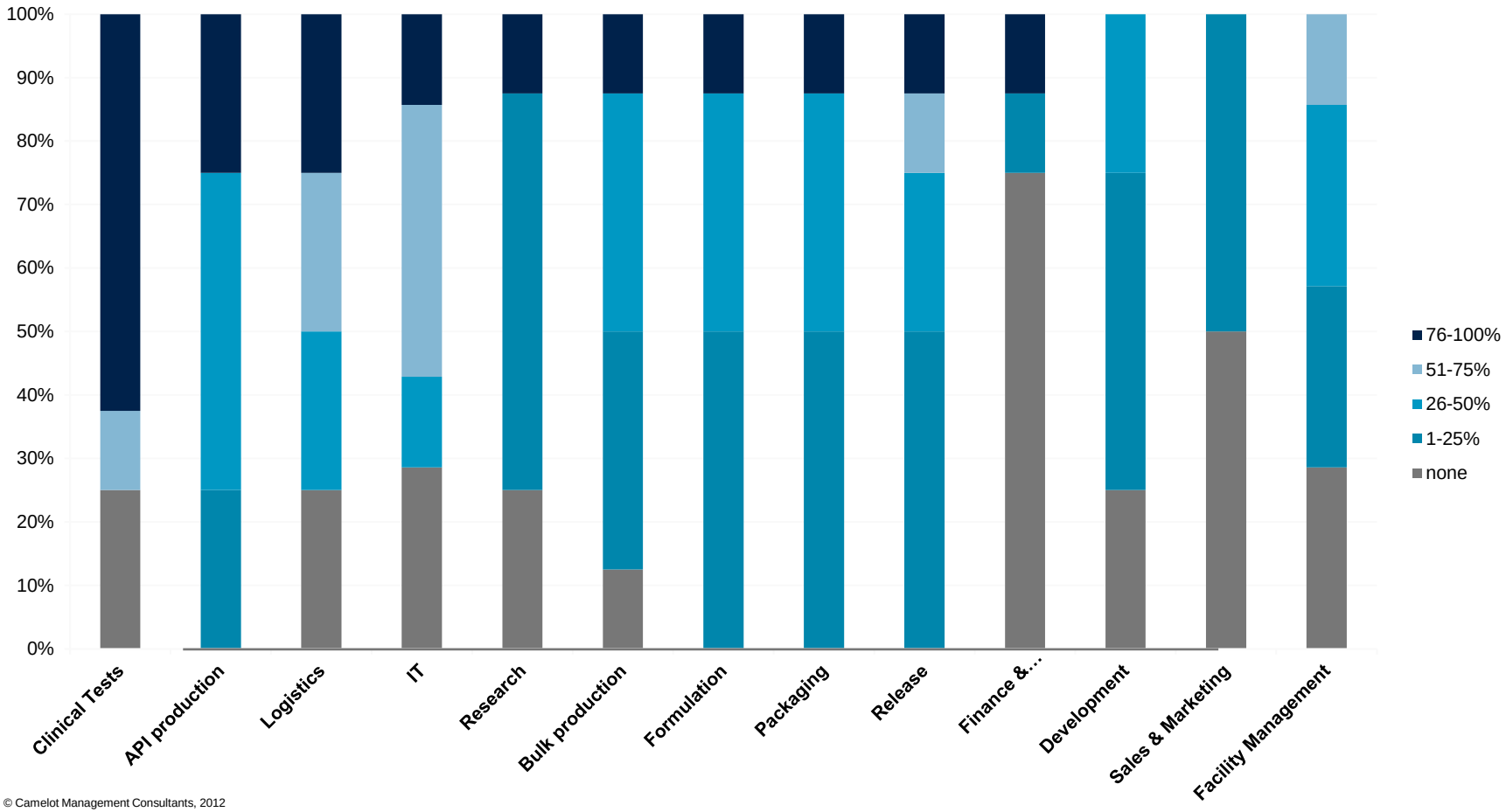
One third of the global pharmaceutical production is considered to be served from emerging economies

Question: Which geographical scope is most appropriate for supply chain disaggregation ?



Pharmaceuticals react on the current circumstances with an increase of outsourcing efforts

Question: „Which proportion of the following functions do you currently source from a third party?“



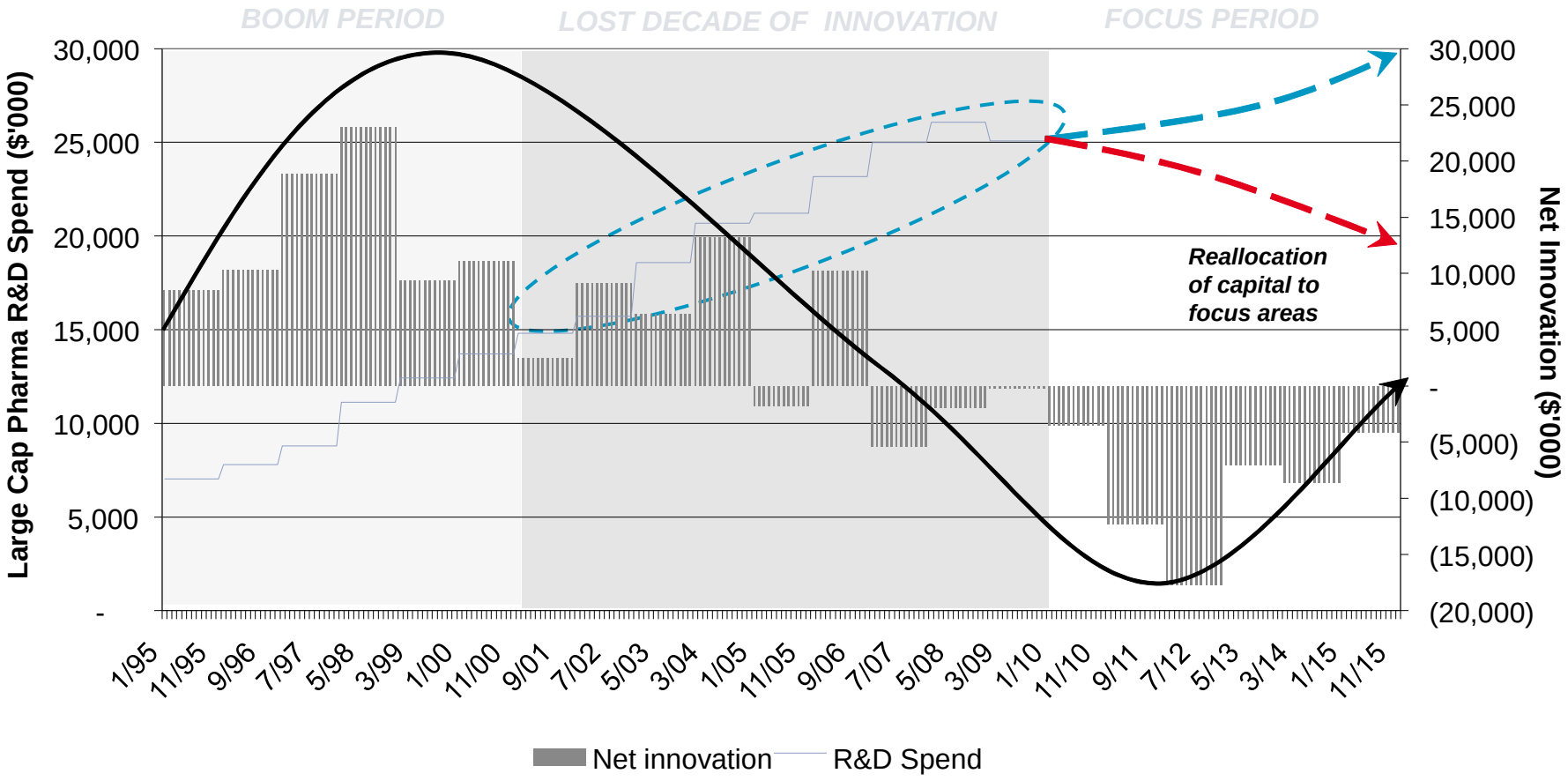
Source: Camelot Analysis

1 The changing environment of serving patients

2 The changing world of Pharma's Business Segments

3 Which initiatives should be directed within the next 5 years

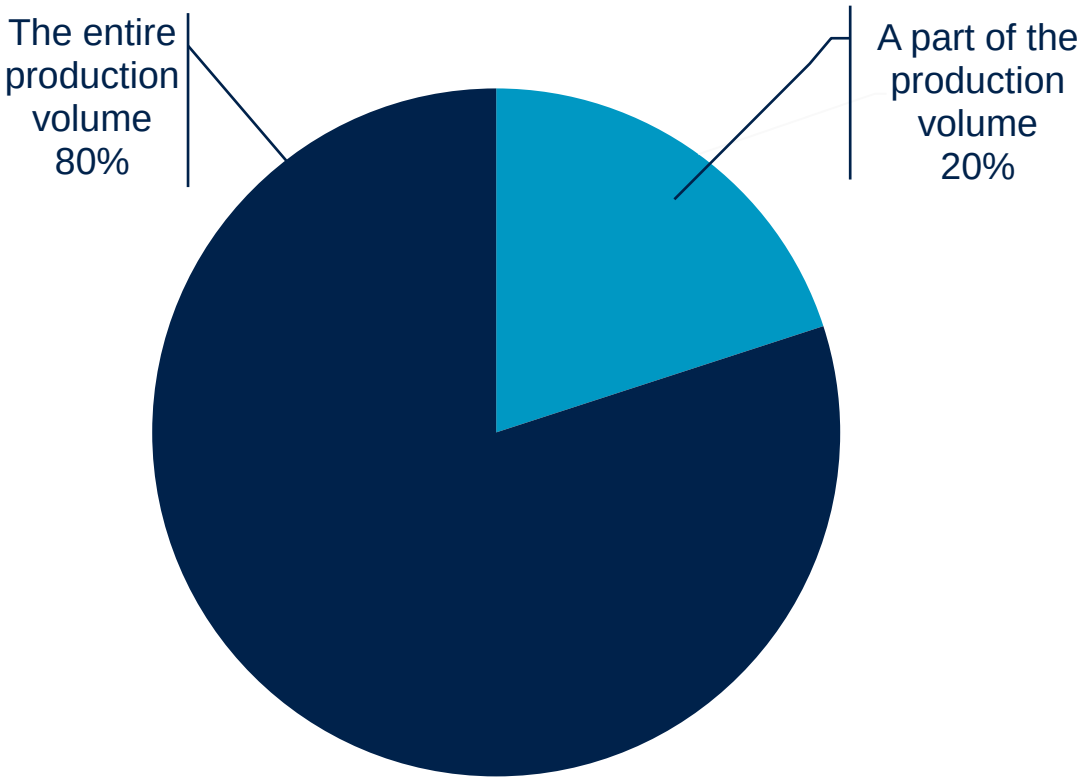
Pharmaceuticals repositioned their business models and started to allocate capital according to the change in business strategy



Note: Net innovation in a given year represents peak life cycle sales for each drug launched that year, less prior year sales for each drug expiring that year.
Source: Goldman Sachs Research, FactSet, company data

In most of the new business models the role of CMO in Pharmaceutical is moving from peak sales mitigating to a strategic partner…

Q: Would you rather source a part of or the entire production volume of one product to a contract manufacturer?



Source: Camelot Analysis

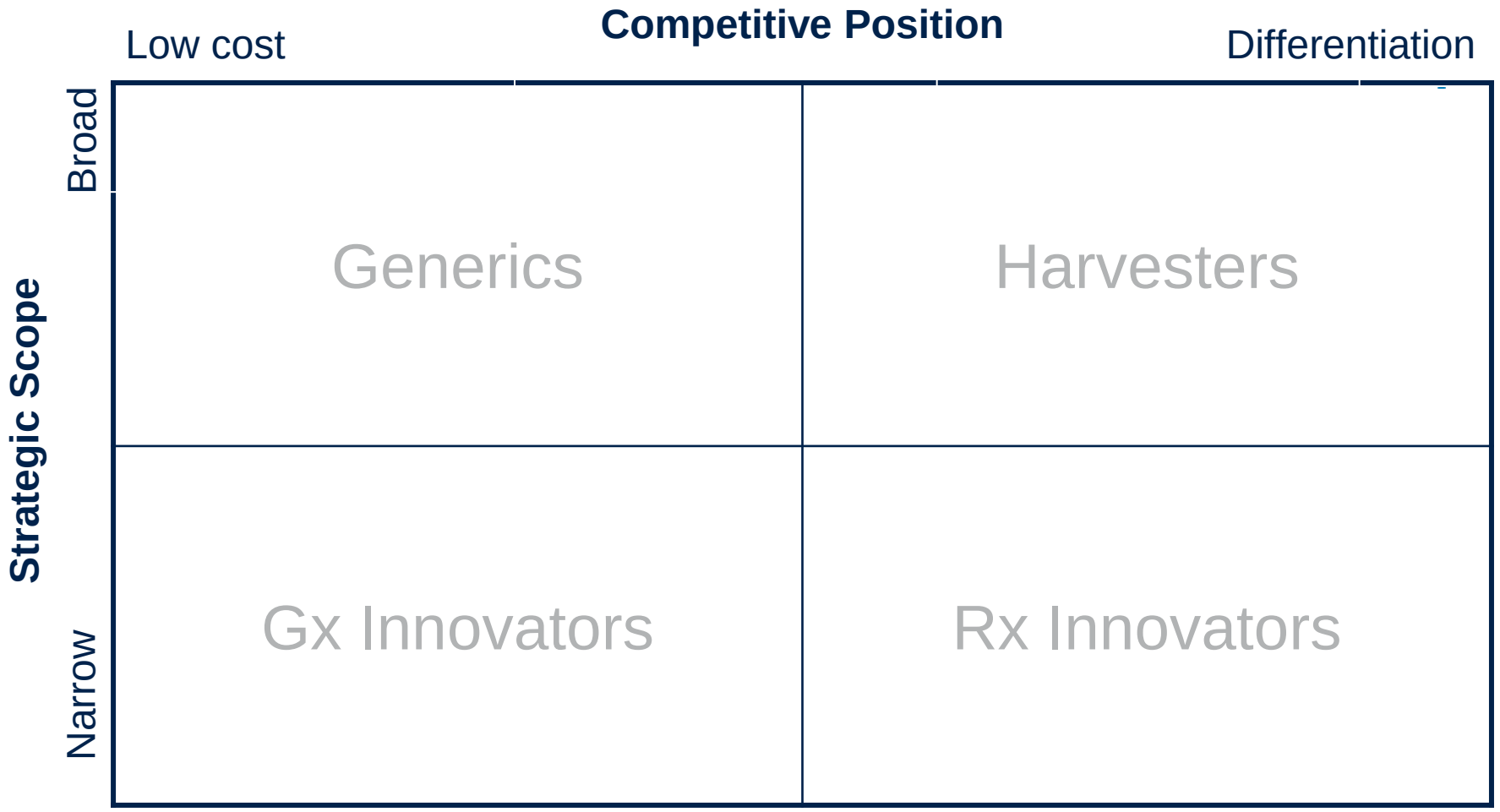
…supplying a big portion of the portfolio volume.

Q: Which proportion of your manufacturing is intended to be sourced from a third party within the years indicated?

Source: Camelot Analysis

Turning away from the blockbuster strategy of the past decade PharmCos developed four different focus lines

ESTIMATION



Note: Estimated strategic scope by sales replacement rate, Competitive advantage by number of Phase III Pipeline products
Source: company data

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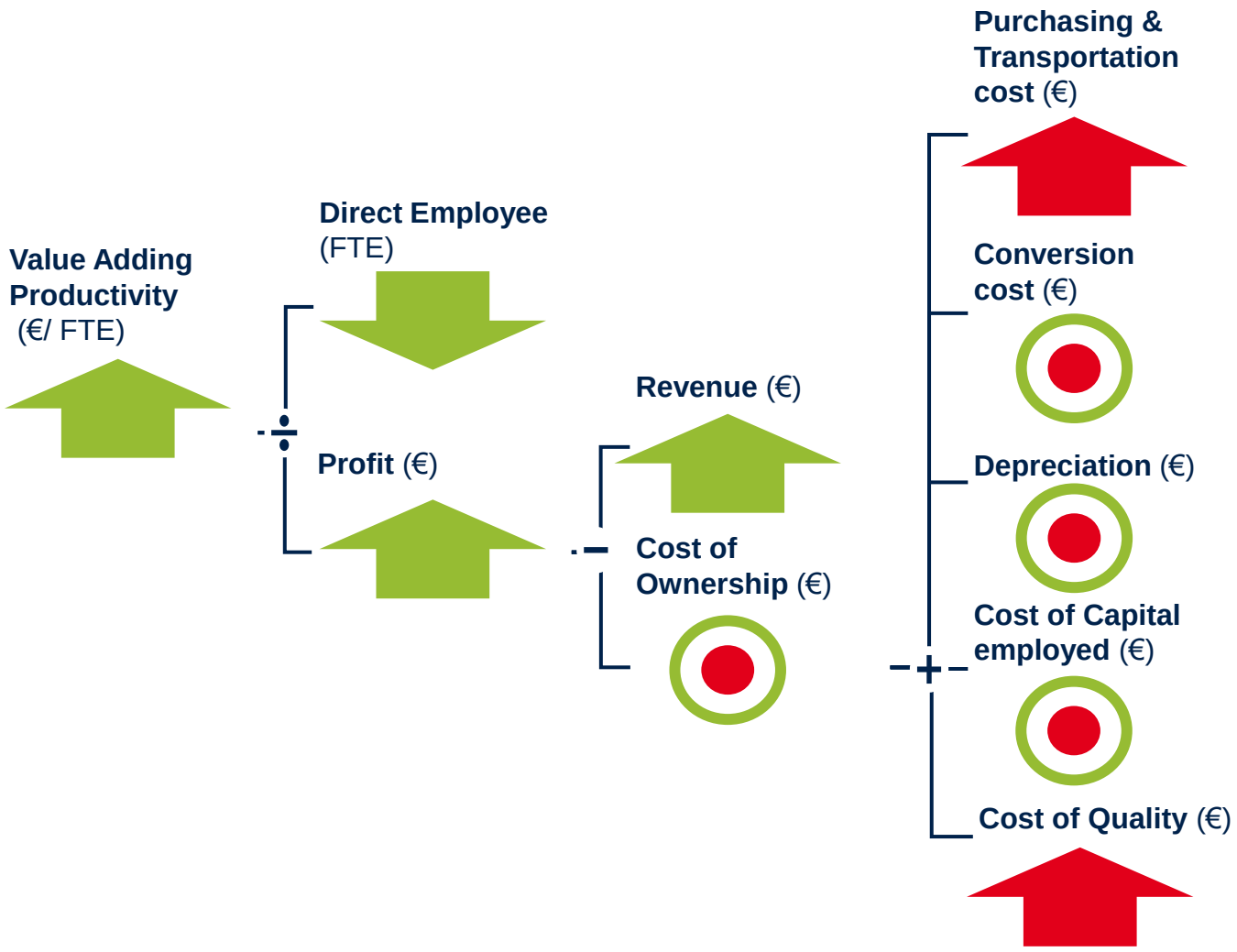
3 Which initiatives should be directed within the next 5 years

What Harvesters do:
Diversifying the existing portfolio geographically and vertically



Est. Changes

- Additional volume outsourced driving Supply Chain cost, but creating additional revenue
- Conversion cost remain the same due to serving “old” SKU along the “old” Supply Chain
- Facilities remain in the network or are sold to 3rd party
- Employed capital remains the same
- Serving from India and China could increase cost of quality on a mid term

Expanding to BRIC MST means serving an increasing number of patients at low cost in more and more protective markets

CHINA

- The pharmaceutical market looks set to grow even further in the short-term, with the establishment of an Essential Medicines System.
- In October 2009, the NDRC reduced the prices of 2,349 drugs by an average of 12%.

INDIA

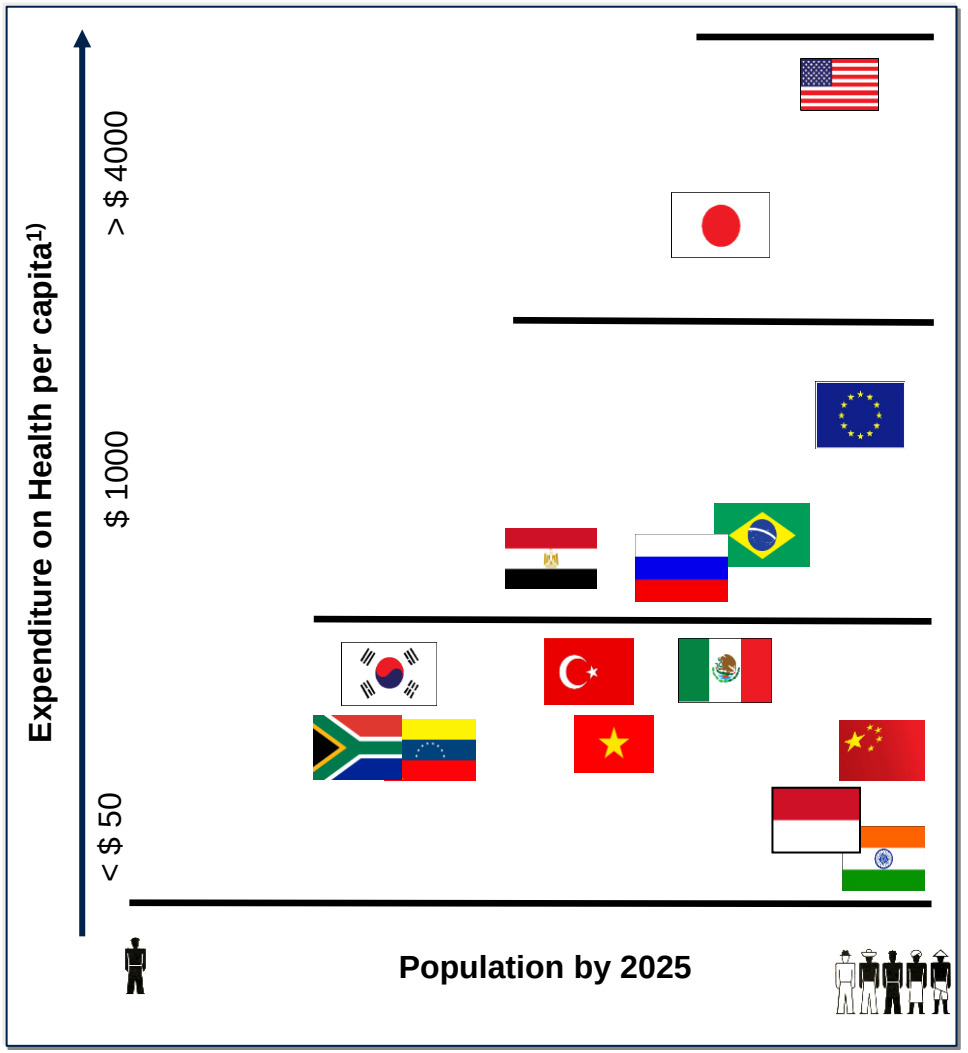
- The majority of the population is both rural and poor
- Established domestic industry, responsible for around 8% of world pharmaceutical production.
- Market is dominated by low price, domestically-produced generics.
- Relatively low per capita expenditure on pharmaceuticals.

BRAZIL

- Second most attractive BRIC market for pharmaceutical producers
- Controlled drug prices are growing at a rate below inflation levels.
- Price controls are not directly linked to consumption levels.
- Indirect tariff barrier to support domestic production

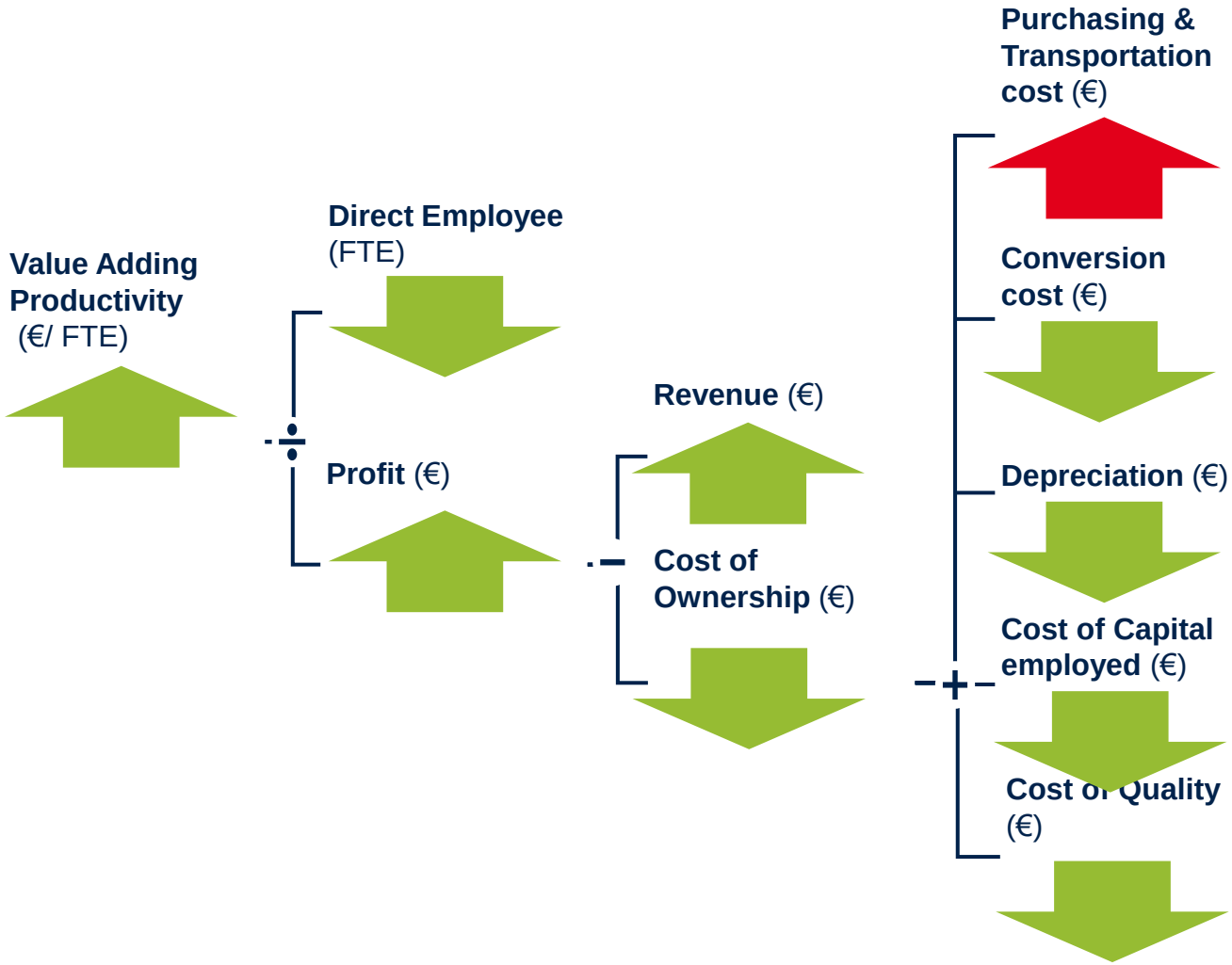
RUSSIA

- In population terms, Russia is a potentially vast market.
- Health spending is very low.
- Around 75% of the pharmaceutical market is supplied by imports.
- Domestic generic industry is sizeable.
- Local production of innovative drugs is negligible.
- Manufacturers are small and under-funded, often producing drugs with outdated equipment.
- Governmental influence on import drug pricing



Notes: 1) public and private spend pre capita 2008
Source: US Bureau of Consensus 2008 , PR Newswire, WHO;

What Rx Innovators do: Divesting the Supply Chain to invest in R&D

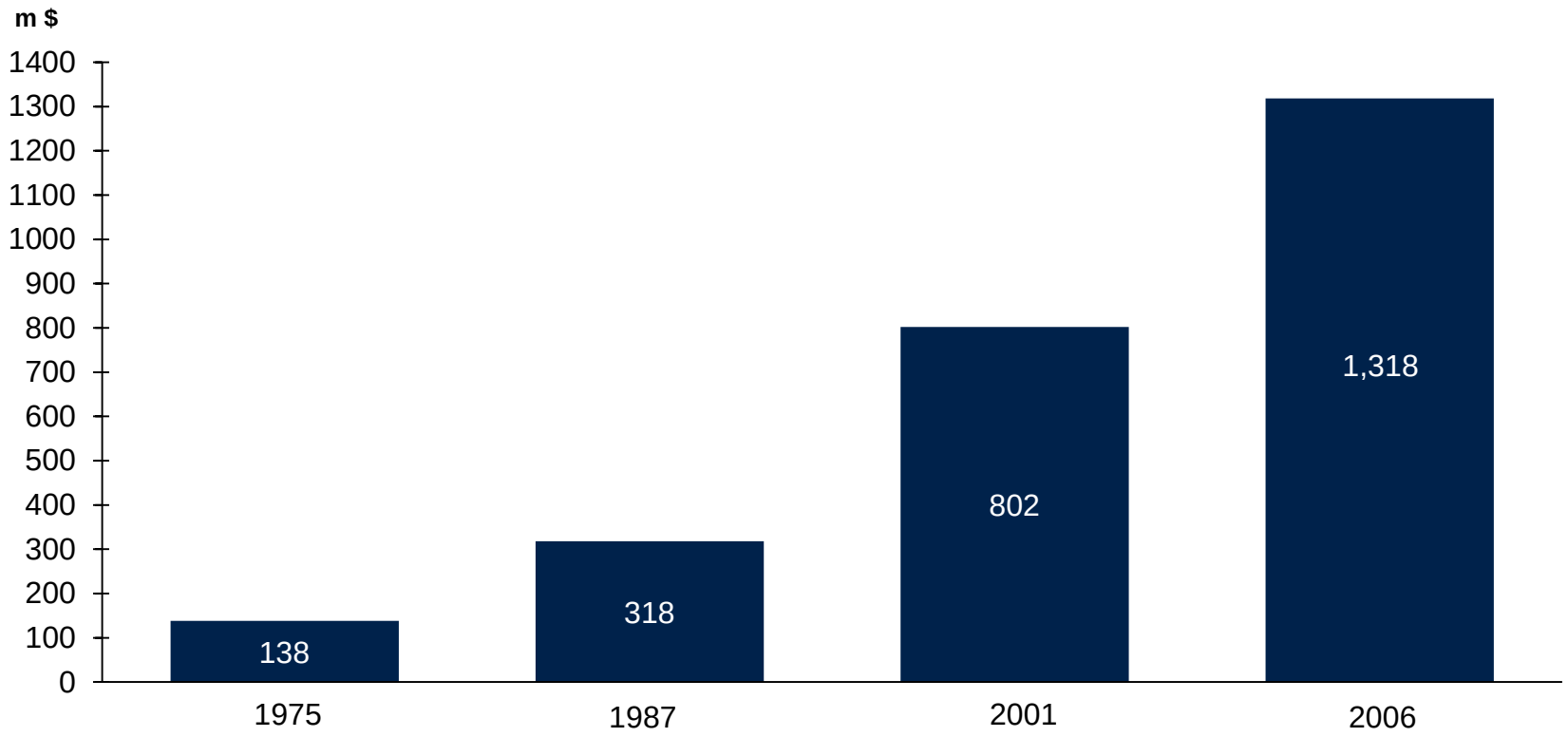


Est. Changes

- Manufacturing and Logistics are not seen as a core competence
- Conversion cost is decreasing due to outsourcing huge volume of expired SKU
- Facilities closed or sold to 3rd party
- Assets are relocated to R&D
- Quality function should be part of the outsourcing service

Rx Innovators enable themselves to cope with these huge investments…

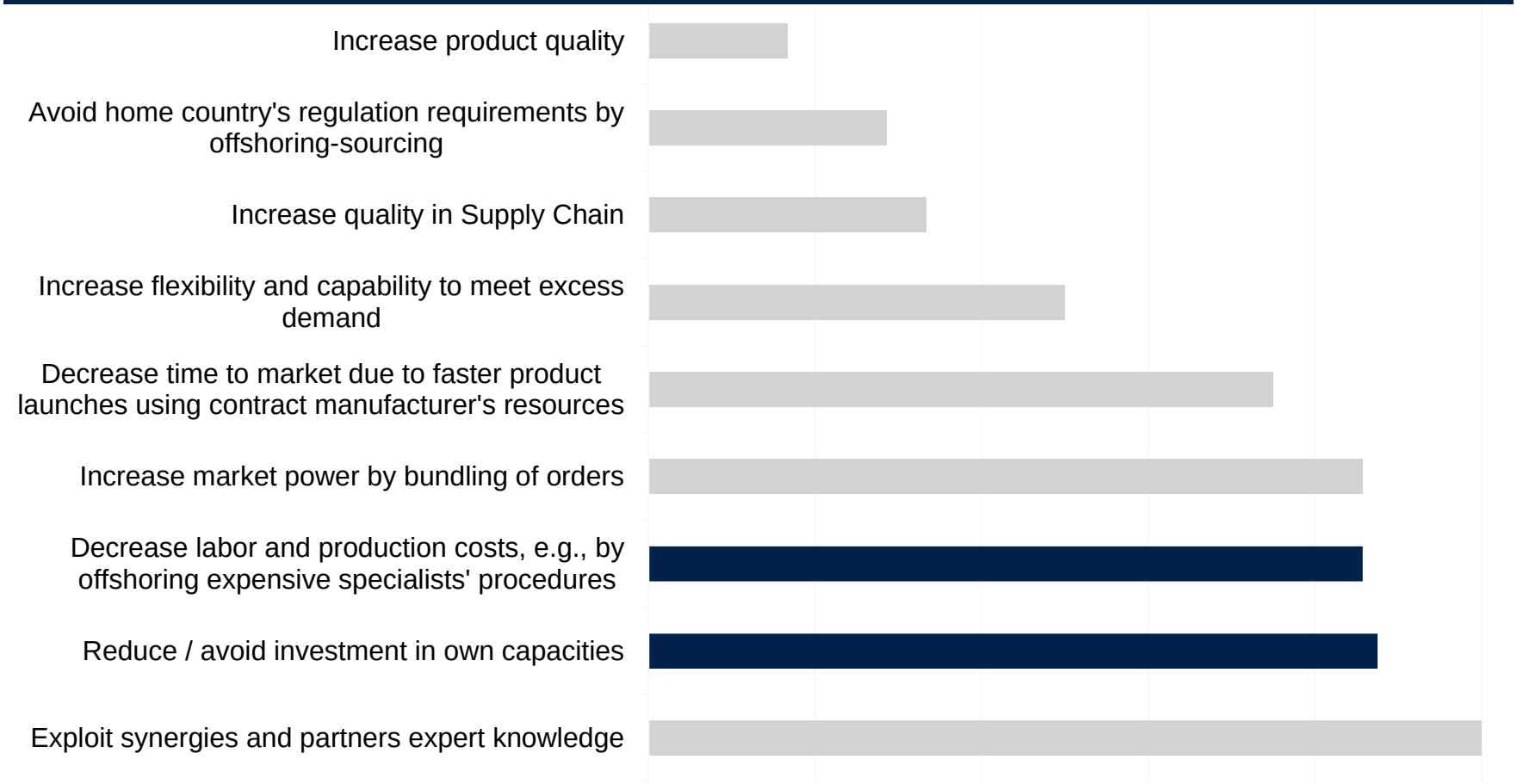
Estimated full cost of bringing a new chemical or biological entity to the market



Source: EFPIA “The Pharmaceutical Industry in Figures”, 2008 edition

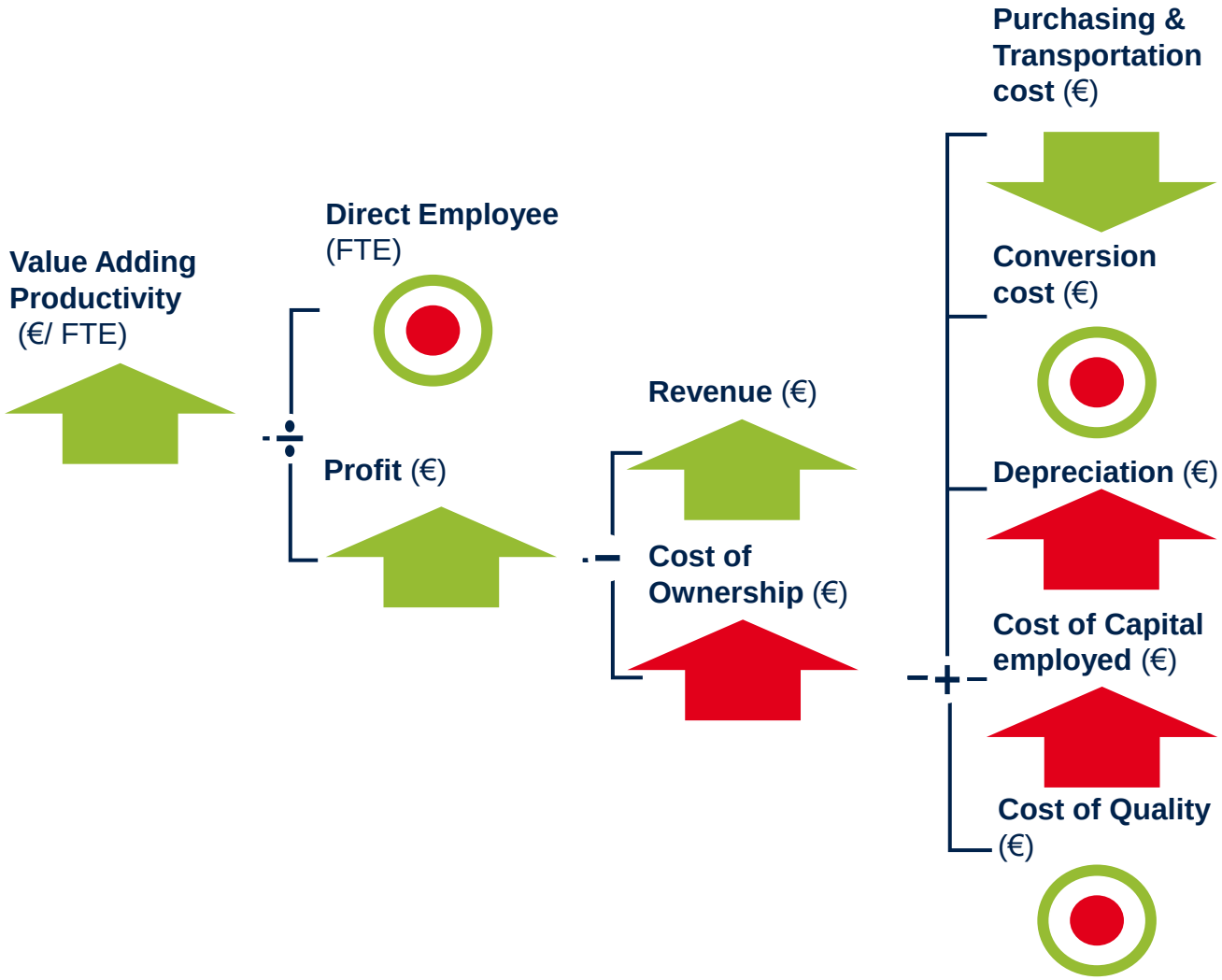
…by divestment of assets. Manufacturing and Distribution is no longer core competence

Question: „Which benefits can be realized when sourcing third party manufacturing?“



Source: Camelot Analysis

What Gx Innovators do: Invest in new capabilities to gain higher revenue



Est. Changes

- M&A activities show that new capabilities come with additional capacity
- The higher number of employee will be covered mid terms by productivity increases
- New facilities remain due to the specialty of technology
- Investment consuming capital
- Serving from India and China could increase cost of quality on a mid term

Gx Innovators investing in Research and Development…

Company	Novel R&D Programs	R&D Spend	Average Spend/Program
Teva	51	$500M	$9.8M
Hospira	6	$161M	$26.8M
Watson	4	$47M	$11.8M
Barr	18	$140M	$7.8M
Dr Reddy's	8	$65M	$8.1M
Ranbaxy	6	$110M	$18.3M
Gedeon Richter	16	$65M	$4M
Apotex	7	$50M	$21.4M
Par	3	$12M	$4M
Glenmark	9	$10M	$1.1M
NPIL	13	$32M	$2.4M
Wockhardt	6	$17M	$2.8M
Torrent	7	$14M	$2M
Dabur	9	$10M	$1.1M
Lupin	6	$35M	$5.8M

Source: ThomsonReuters

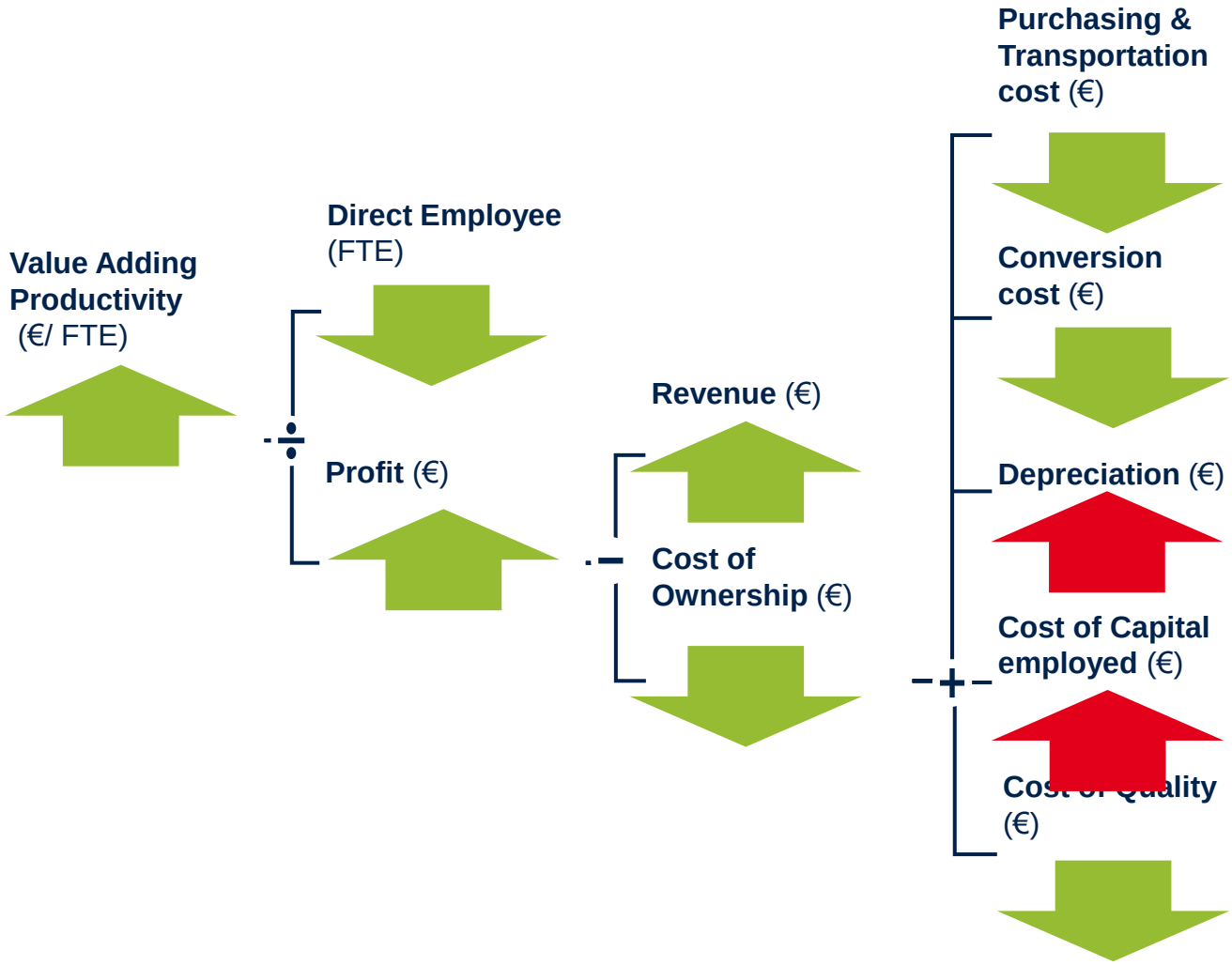
… and show significant success by generic versions of biotech products ("biosimilars")

Company	Proteins	Antibodies	Vaccines	Launches
Teva	■	■	■	EPO,GCSF
Sandoz	■	■		EPO, HGH
Biocon	■	■	■	GCSF
Hospira	■	■		EPO,HGH
Zydus	■	■		GCSF
STADA	■	■		EPO
Actavis	■			Via Bioton
Ranbaxy	■	■	■	
Dr. Reddy's	■	■		GCSF
Apotex	■	■	■	
Cipla	■	■		

■ Under development ■ Full production

Source: ThomsonReuters

What do Generics do: Virtualizing the Value Chain to take a share of the Pharmerging growth



Est. Changes

- M&A activities show that new capabilities come with additional capacity
- The higher number of employees will be covered mid terms by productivity increases
- Increasing network as a side effect of M&A deals
- Investment consuming capital
- Quality function should be part of the outsourcing service

Generics buy existing business to serve at low cost

Company	Target company	$ billion	Technology/product
J&J	Pfizer OTC	16.6	Consumer health
Teva	Barr-Pliva	7.5	Generics
Teva	Ivax	7.4	Generics
Novartis	Eon	6.8	Generics
Mylan	Merck KGA generic	6.7	Generics
Novartis	Hexal	5.3	Generics
Teva	Ratiopharm	5.0	Generics
Daiichi Sankyo	Ranbaxy	4.0	Generics
Teva	Sicor	3.4	Biosimilars
Sanofi Aventis	Zantiva	2.6	Generics
Barr	Pliva	2.5	Generics
Reckitt Benckiser	Adams respiratory	2.3	Generics
Sanofi Aventis	Chattem	1.9	Consumer health
Watson	Andrx	1.9	Generics
Watson	Arrow	1.75	Generic Lipitor

Source: Knol: Mergers & Acquisitions Review 2005-2011 Pharma Biotech

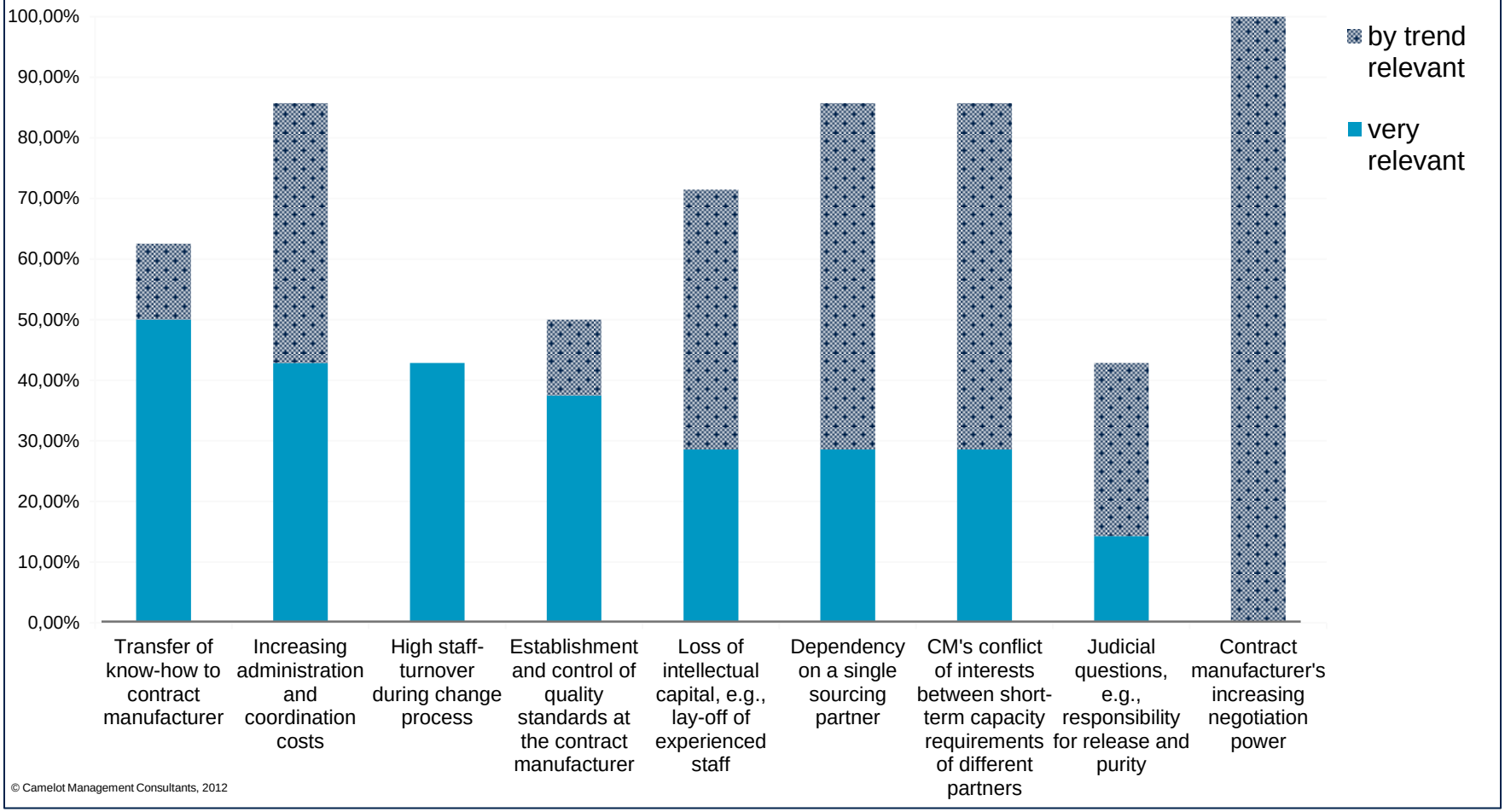
1 The changing environment of serving patients

2 The changing world of Pharma's Business Segments

3 Which initiatives should be directed within the next 5 years

Facing the new future experts see several constraints to overcome within the next 5 years

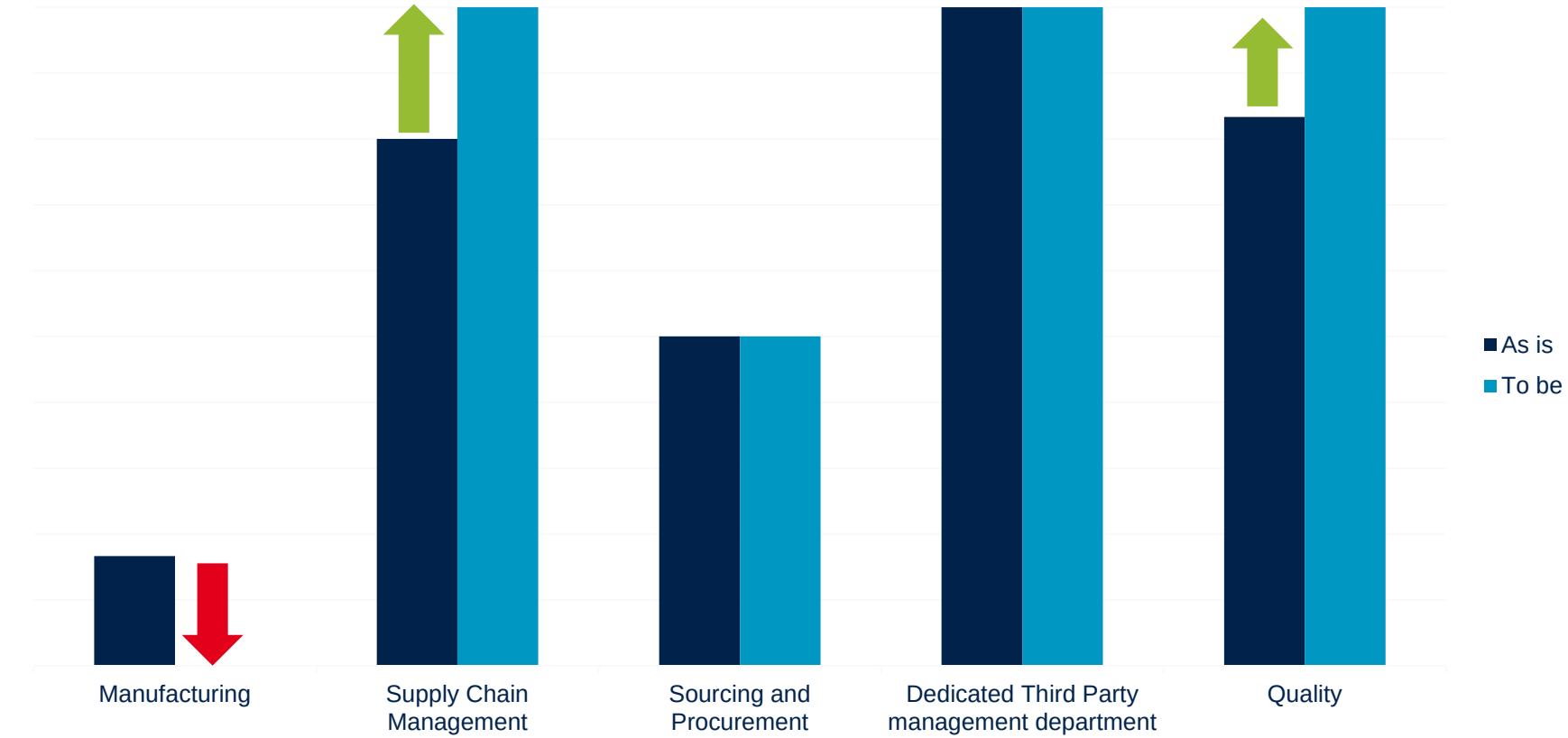
Question: „Which threats do you suspect when sourcing manufacturing?“



Source: Camelot Analysis

Global SCM is intended to take the lead to build and manage the global external supply network, taking the responsibility from local manufacturing

Question: „When do the following functions communicate with the contract manufacturer?“



Source: Camelot Analysis

To centralize the management of an external network four steps should be considered

Manage

- Review network performance
- Identify improvement opportunities
- Phase out underperformers
- Develop new champions

Grow

- Grow supplier network by development plan
- Grow own network management capabilities
- Grow collaboration with strategic supplier
- Grow trust

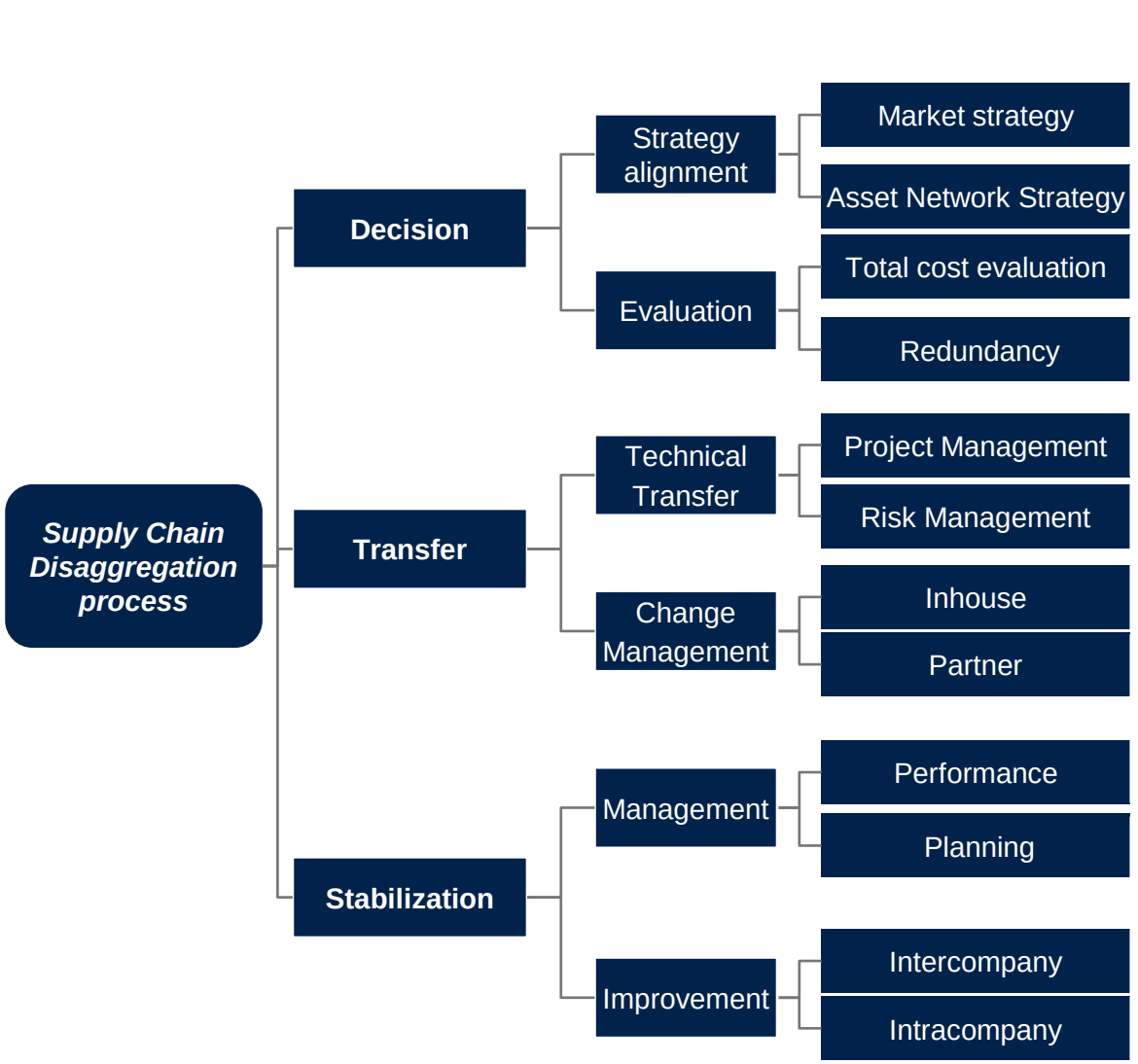
Assess

- Assess supplier performance
- Assess suppliers risk
- Assess own network management capabilities

Map

- Map candidate products for outsourcing
- Map existing supplier landscape
- Map Supply Chain Network
- Map current against future markets

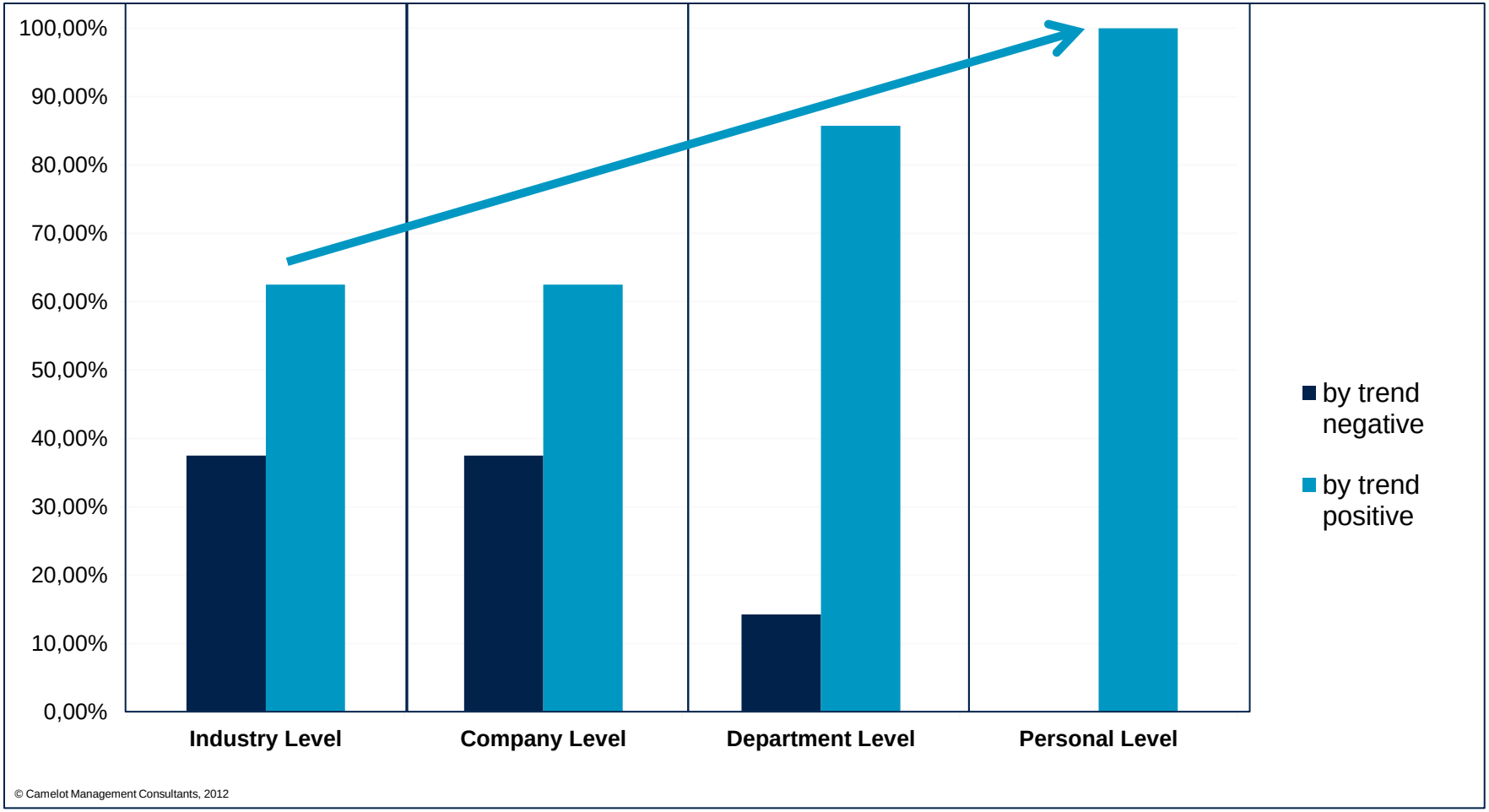
Pharmaceutical outsourcing officers should ask themselves some key questions to identify how good the company is prepared



Key Questions
How we intend to supply the relevant market?
How we able to gain advantage of outsourcing?
Is the outsourcing intension cost effective?
Could we reduce own assets ?
Is the transfer manageable?
How to manage the risk a transfer bears?
How we manage internal turmoil?
How we prepare our partner?
How we measure the partners performance?
How we provide the information needed?
Which are the mid term aspirations for the link management?
How we improve our own and partners processes?

There is a long way to go to change behavior toward the new reality

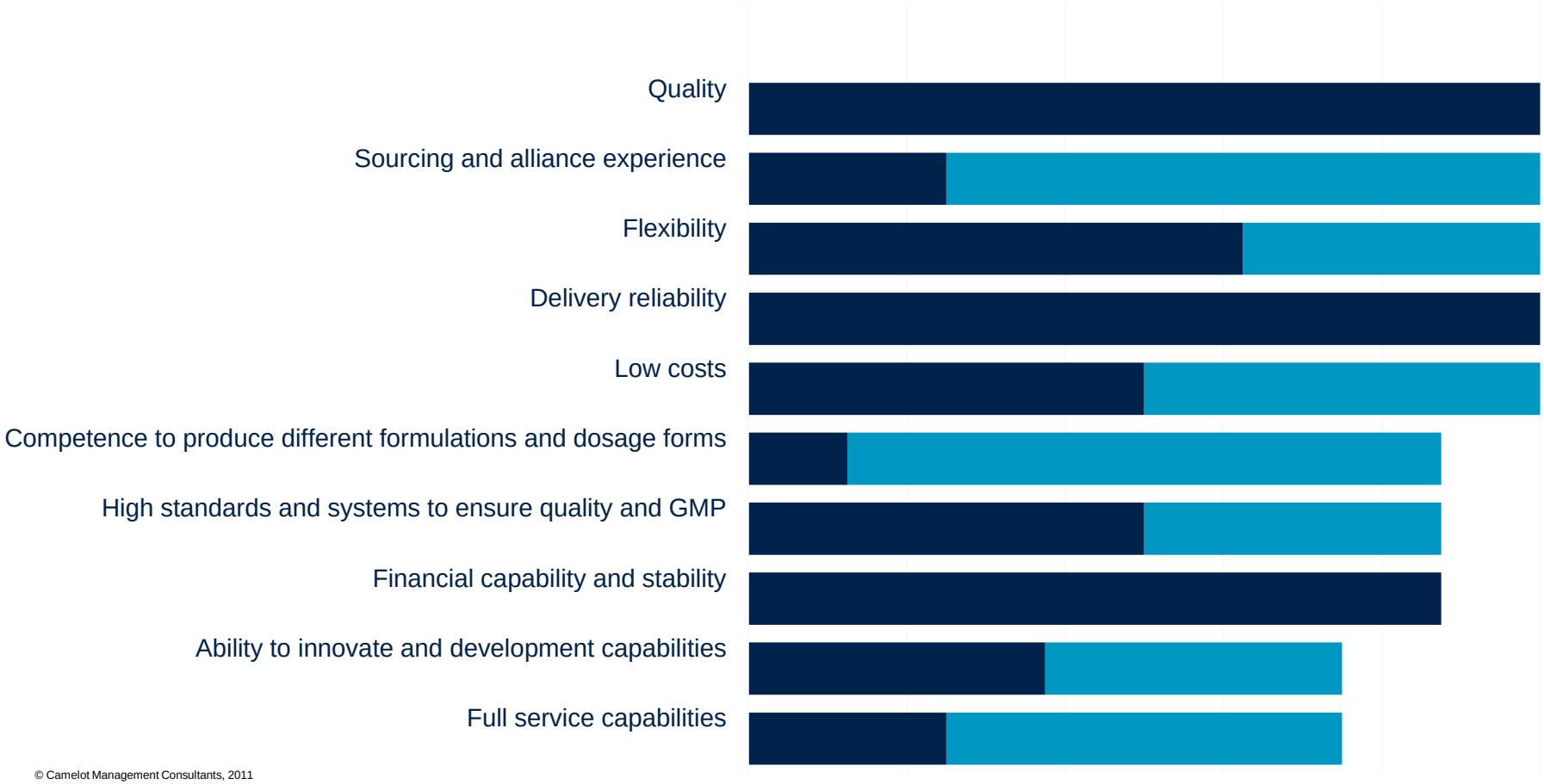
Question: „What is in your opinion the attitude towards supply chain disaggregation?“



Source: Camelot Analysis

While quality and delivery reliability should be given, 3rd party providers face the chance to gain big volume products supply on full service…

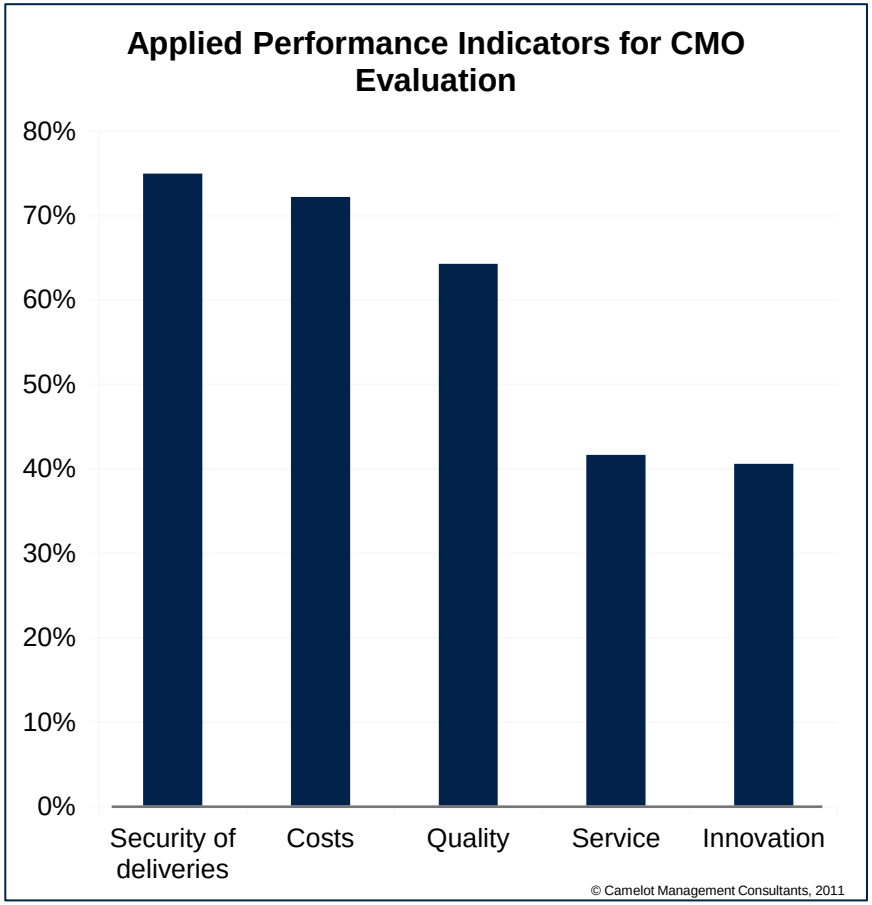
Question: „Which of the following characteristics make a contract manufacturer attractive and to which degree?"



Source: Camelot Analysis

… and act as an integrated part of the Supply Chain

Q: „Which of the following performance indicators do you apply to manage your contract manufacturer‘s performance?“



75% Security of Deliveries
- Adherence to delivery terms (OTIF)
- Planning adherence (communicated changes)

72% Costs
- Revised price
- Offer price
- Total cost of ownership

64% Quality
- Quality KPI
- Handling (look and feel)
- Compliance (complete and correct docs.)

42% Service
- Flexibility
- Order confirmation rate
- Invoicing

41% Innovation
- Suggestions for improvement
- Investments
- Documentation of workflows

Source: Camelot Analysis

For further information please contact

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