

The Pharmaceutical Industry and the Industrial Pharmacist: A Partnership for the 21st Century

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These are troubled times.....

the **guardian**

€90bn Irish bailout ends in turmoil.
Now Europe fears crisis will spread

the **guardian**
weekend edition

Warning that UK 'may never
recover' if Greece exits euro

Champions League:
it's the final
European coverage of
the game of the year



BBC

Greek austerity plans not ready, say eurozone ministers

Eurozone ministers have cast doubt on
Greece's ability to push through
austerity measures needed to release a
130bn euro (\$170bn; £110bn) bailout.

At a meeting of finance ministers in Brussels,
Germany's Wolfgang Schaeuble said a plan
agreed by Greece's fragile coalition after
days of talks was "not at a stage where it can
be signed off".

The EU and IMF demanded stringent cuts in
return for the bailout money.



German Finance Minister Wolfgang Schaeuble:
Negotiations 'haven't come far enough'

Recession causes doubts over Italy's deficit cut plans

By Guy Dinmore
in Rome and
Peter Spiegel in Brussels

Italy's ambitious deficit
reduction targets could be
jeopardised by recession
and high interest rates that

tively high interest rates.
The government should
stand ready to avoid any
slippage in budgetary exe-
cution and take further
action if needed.

The report, prepared by
the European Commission's

believes, now the
the peripheral in
the eurozone.

In an interview
sidelines of the
Ambrosiotti finan-
forum in Cernobbio
Mr Koo outlines
theory of "balanced
recessions", while
against current
orthodoxy.

When countries
Japan, experienced
in asset prices,
traumatised priv-
companies, bank
households will
everything possi-
deleverage their
sheets and pay
debt. In such

These are troubled times.....



These are troubled times.....



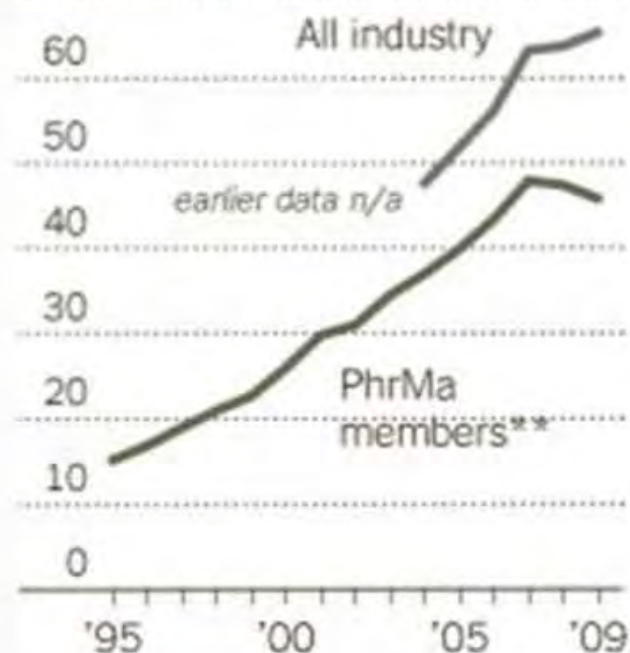
.....and *pharma* is not 'immune'.

Fewer New Drugs Gain Approval

Pharmaceutical companies have spent more on research and development over time, but have discovered fewer novel drugs good enough to gain F.D.A. approval.

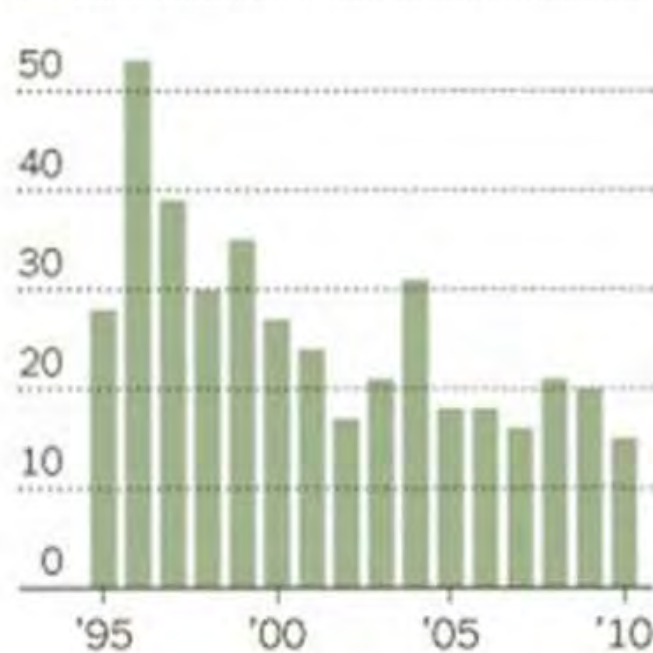
PHARMACEUTICAL R&D EXPENDITURES

\$70 billion



NEW DRUGS APPROVED*

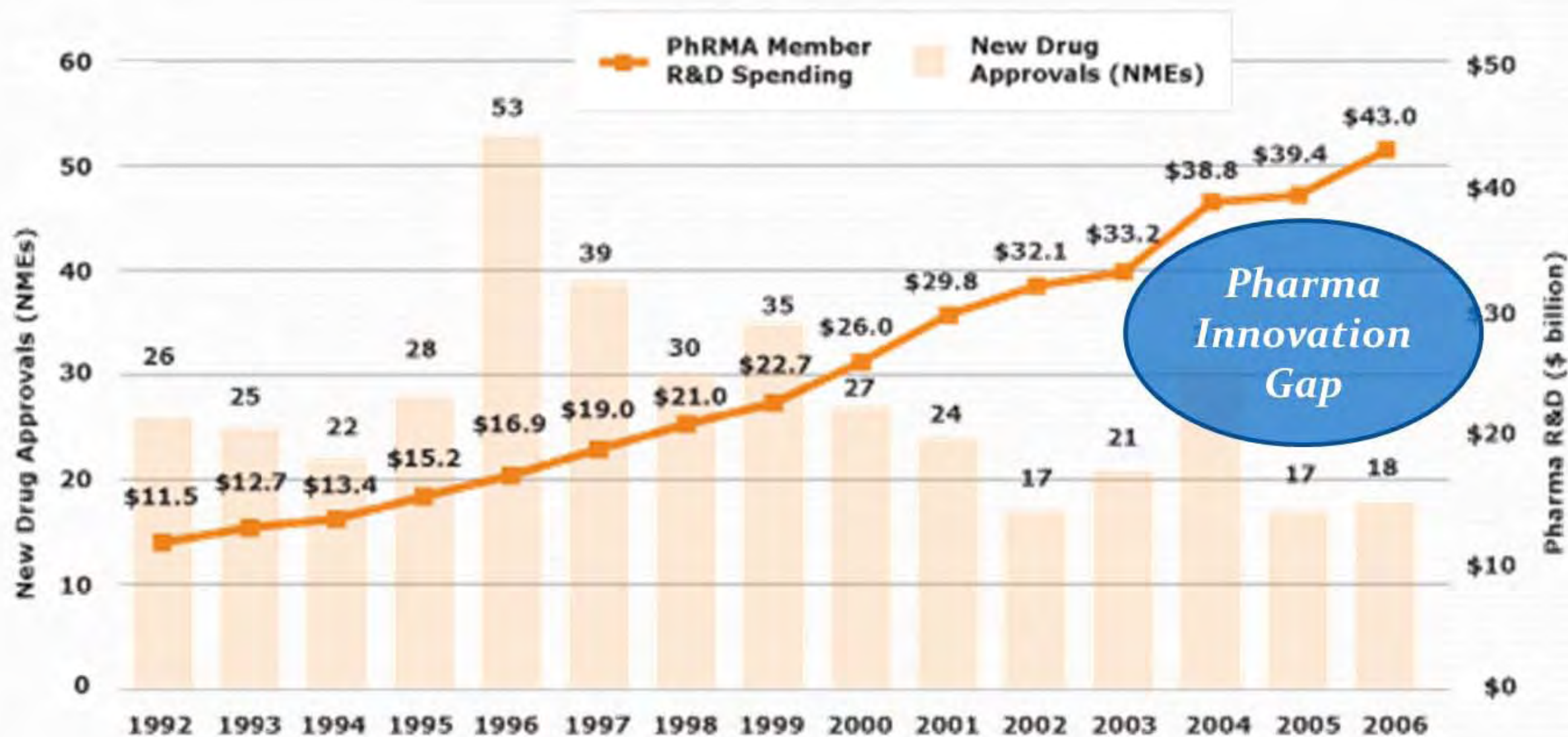
60



* Does not include biologics. **Pharmaceutical Research and Manufacturers of America, or PhRMA, includes most of the major U.S. pharmaceutical research and biotechnology companies.

Sources: Food and Drug Administration;
Pharmaceutical Research and Manufacturers of America

.....and pharma is not 'immune'.



Source: Burrill & Company; US Food and Drug Administration

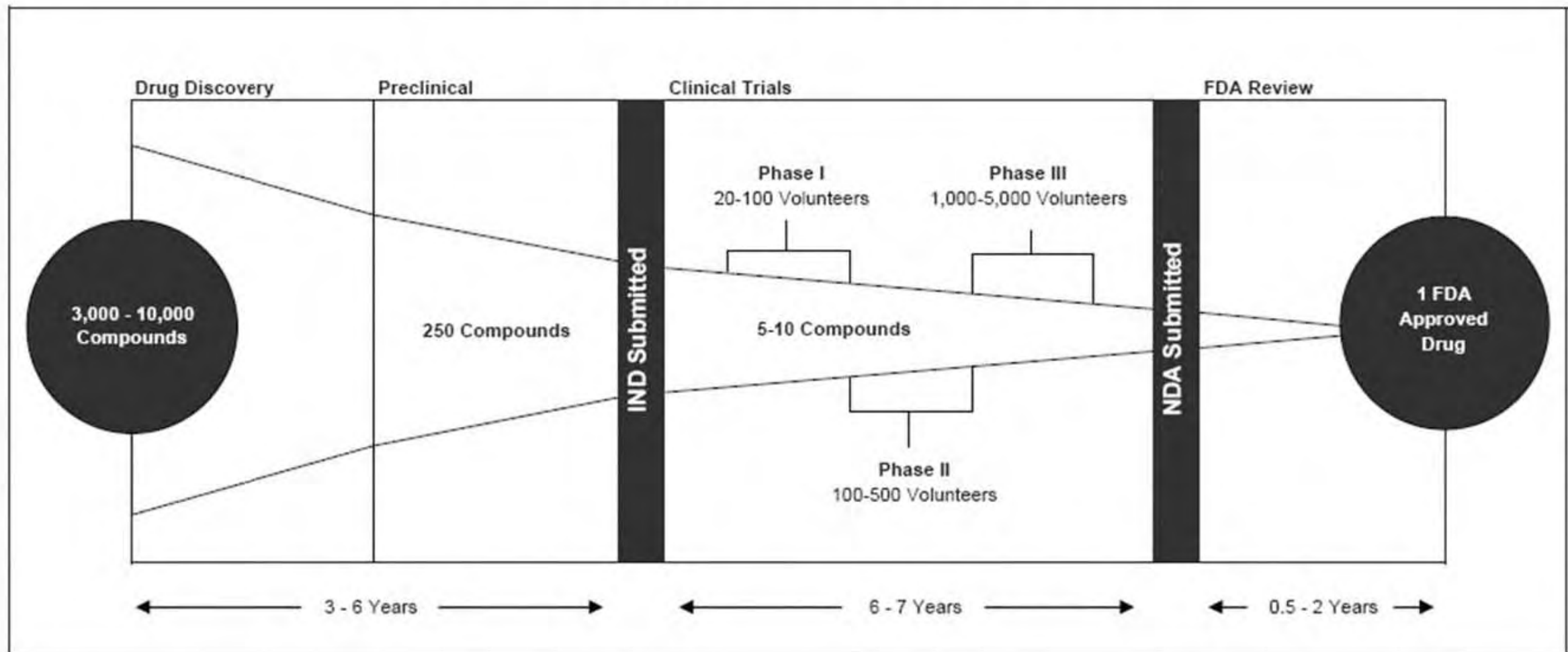
Drug Development is a Costly Business

The cost of producing a successful marketable product was approximately €980 million in 2006

- Figure includes both the cost of the successful candidate and those of the failures.
- Failures represented over 70% of the total cost in 1995.
- Only 34% of new drugs introduced between 1990 and 1994 registered revenues that exceeded the average research and development cost (blockbusters).
- In 2003 it was estimated that in order to maintain a healthy revenue growth rate of 10%, the ten largest pharmaceutical companies would need to launch about three new compounds per year. Less than two launches per company were actually achieved in 2000.

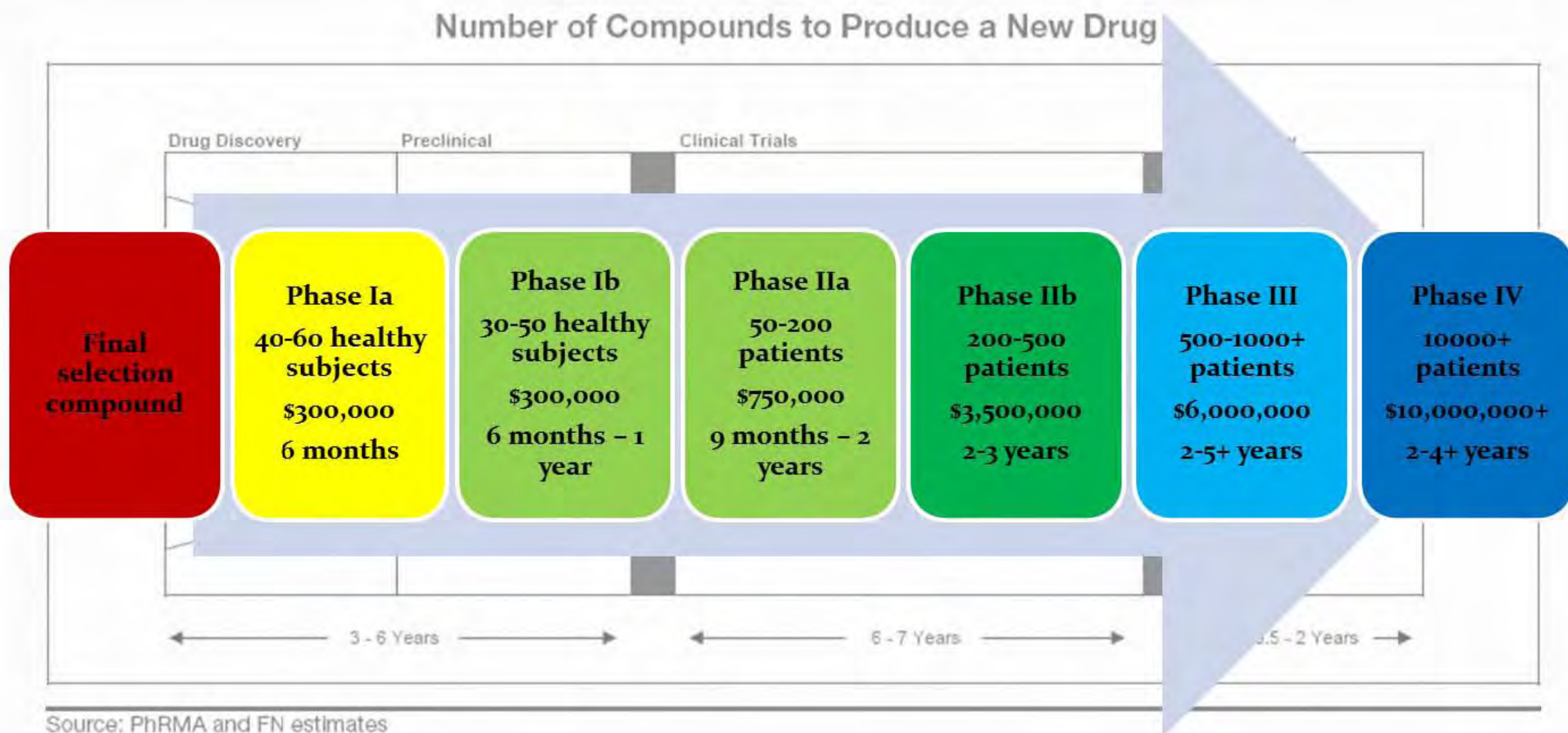
Drug Development is a Costly Business

Number of Compounds to Produce a New Drug



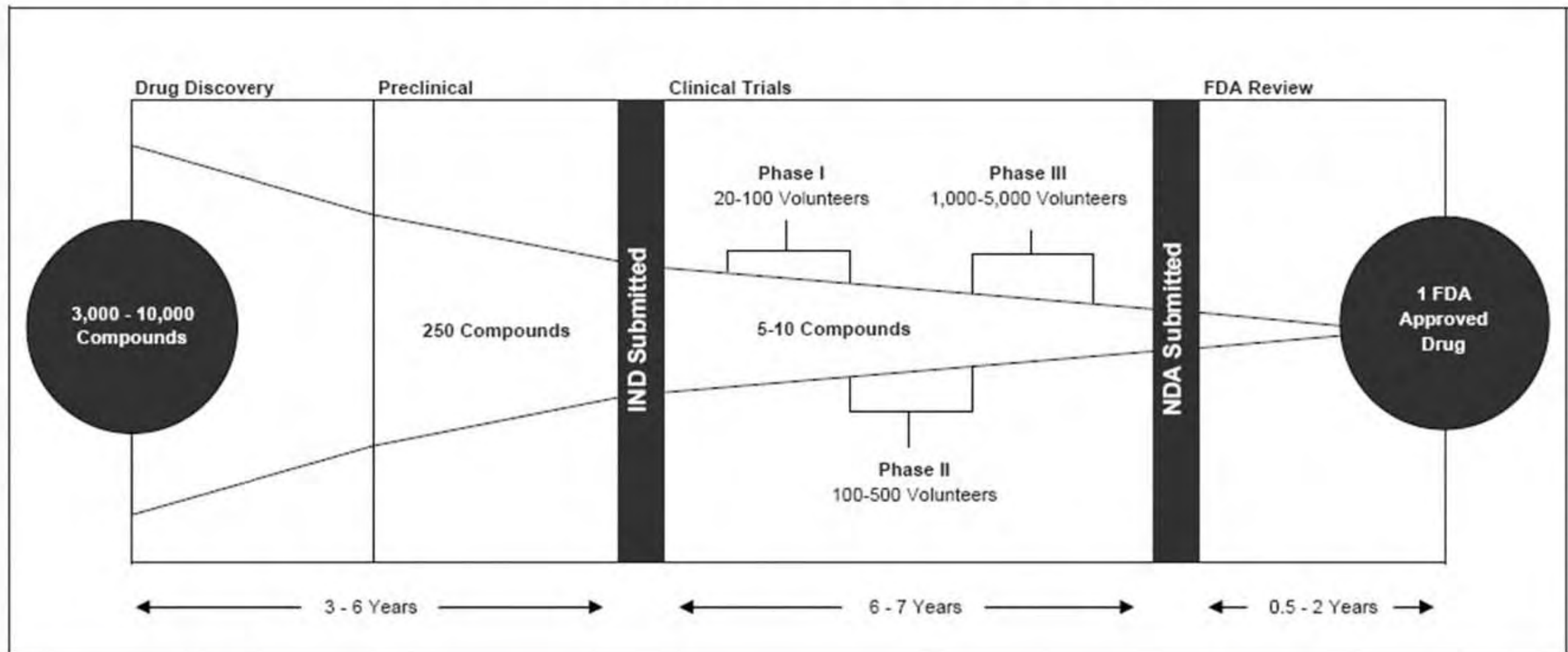
Source: PhRMA and FN estimates

Drug Development is a Costly Business



Drug Development is Time-Consuming

Number of Compounds to Produce a New Drug

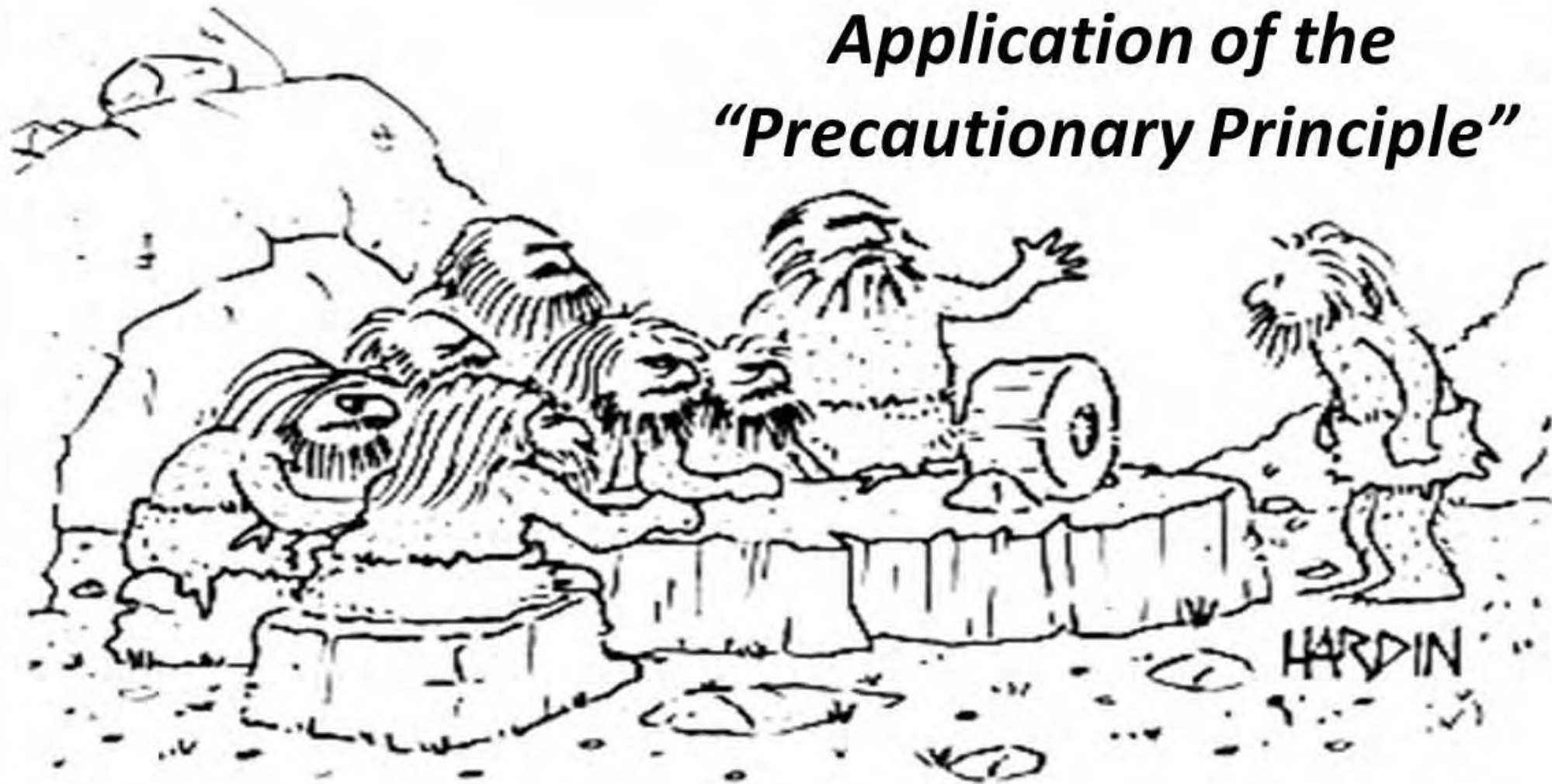


Source: PhRMA and FN estimates

10-15 years from start to launch

Growing Regulatory Conservatism

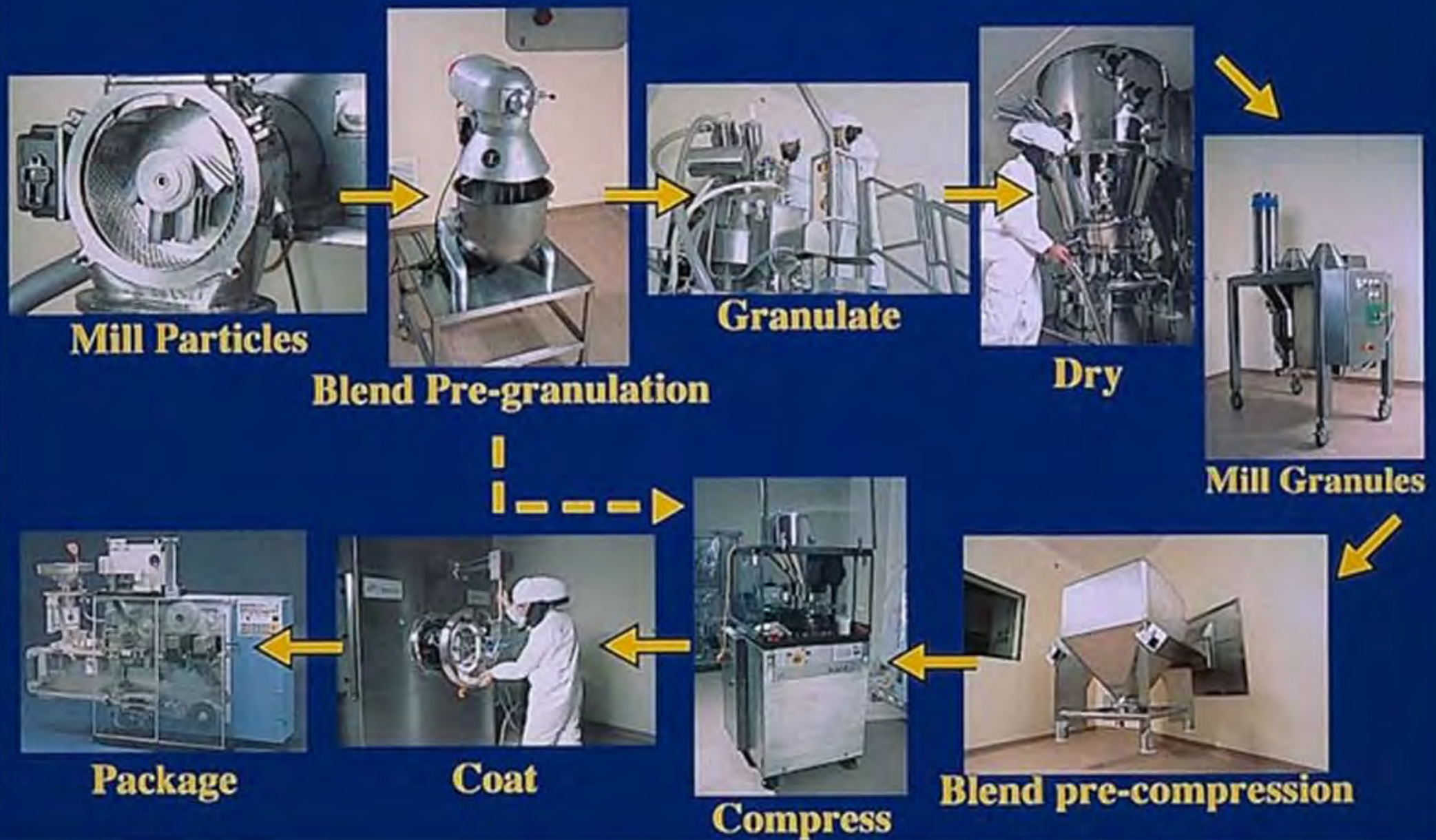
Application of the “Precautionary Principle”



“The Committee’s decided to ban further research until it can be proven your ‘wheel’ poses no threat to the environment, society or public health”

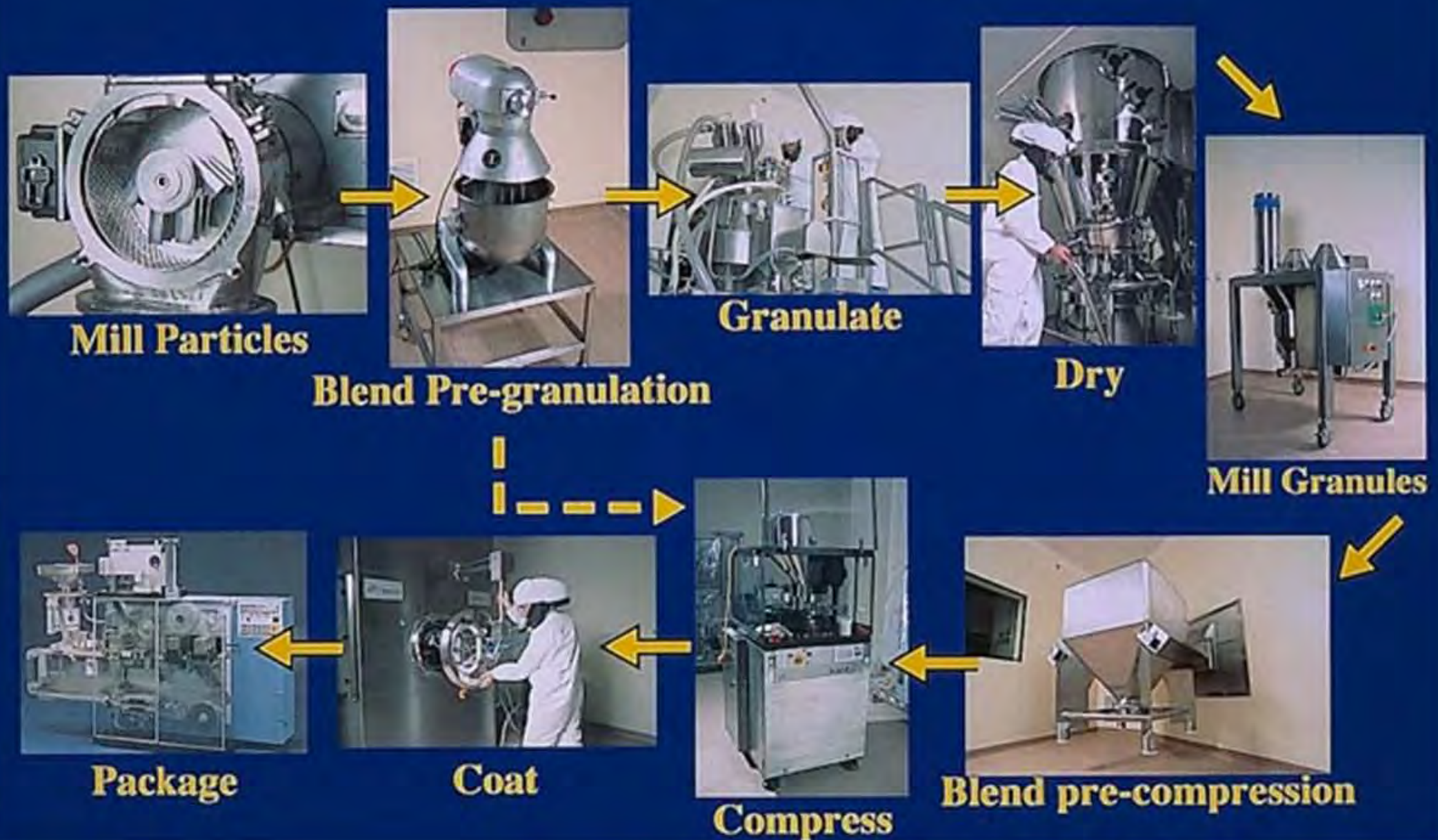
Technology Stagnation

Formulation in 1970



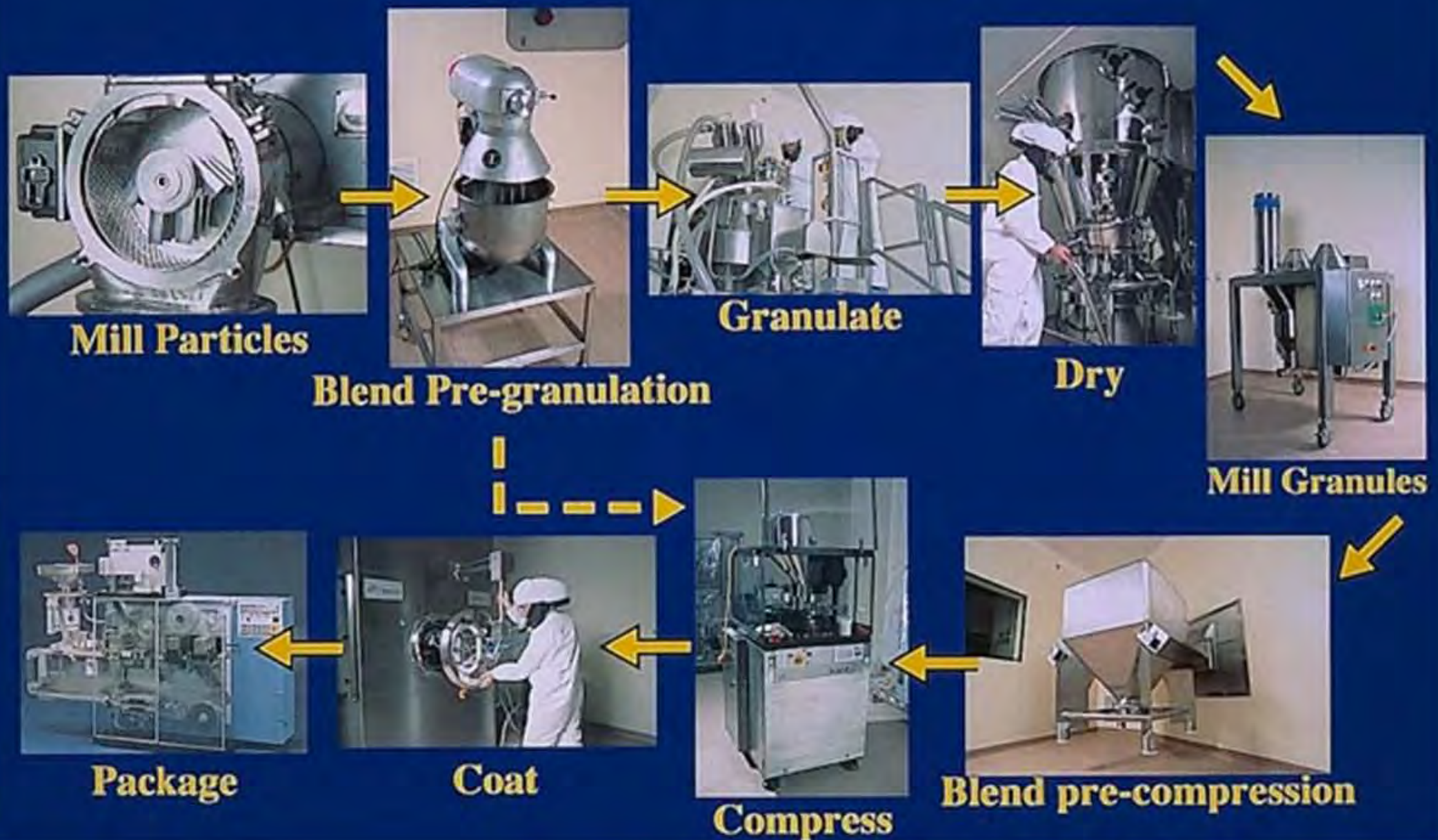
Technology Stagnation

Formulation in 1990



Technology Stagnation

Formulation today



Technology Stagnation

- **2004:** Waters introduces the first of its ultra-high performance liquid chromatography instruments (Acquity UPLC®), capable of withstanding the high pressures associated sub-2 μm particle column technology.
- **2006:** Waters launches Acquity UPLC® H-Class for researchers “who have been attracted by the promise of UPLC but remain reluctant to change largely because of their comfort levels with existing HPLC systems and techniques” (Rohit Kanna, Waters VP of worldwide marketing).
- **2012:** Legacy methods are still running under HPLC quaternary methodology. Companies try to obtain advantages of sub-2 μm particle columns on regular HPLC instruments, or change to core-shell columns, but few, if any, migrate to ultra-high performance liquid chromatography.

Just to put things in perspective...

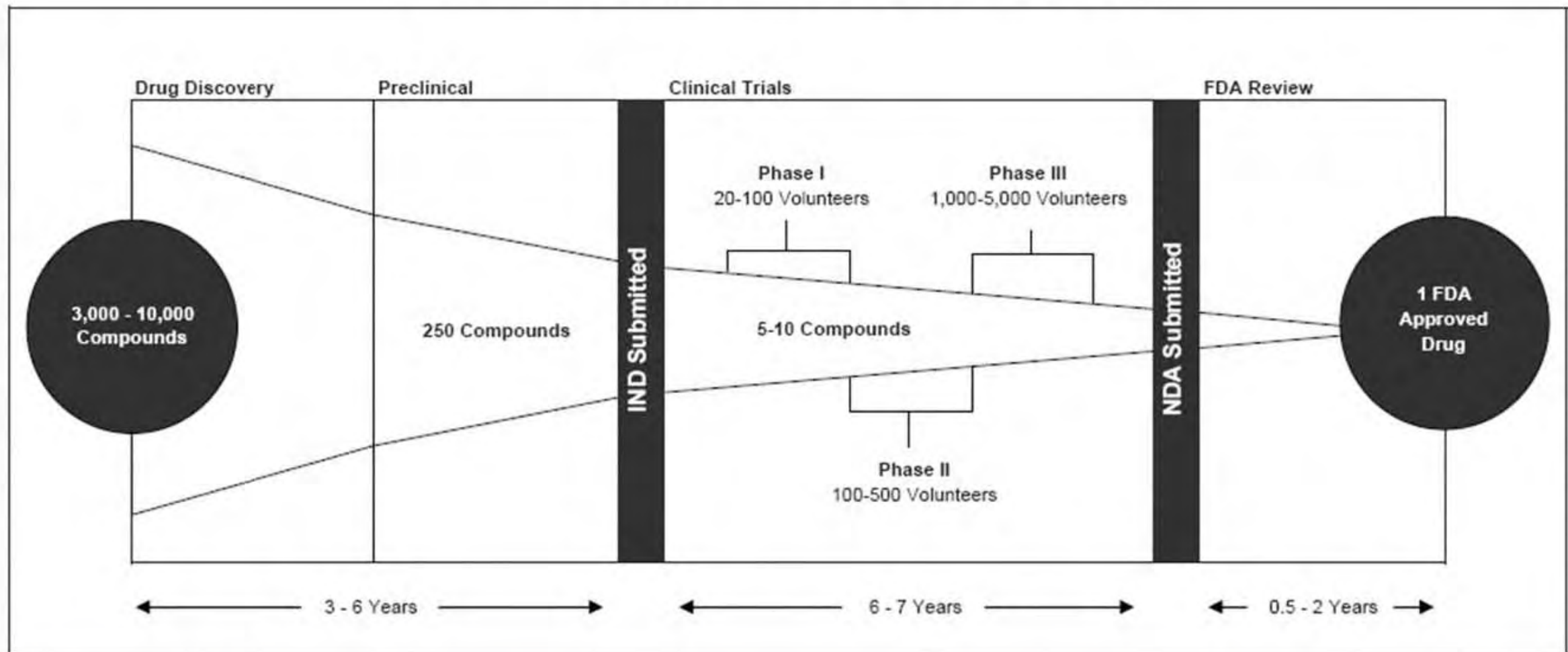


Consequences of Technology Stagnation

- Production and quality control are not state-of-the-art compared to other industries.
- Products are of good quality, but this comes at great effort and cost compared to other industries.
- High manufacturing costs are compounded by the use of technologies that are inefficient by modern standards.
- Technology stagnation in manufacturing and analysis acts as a bottleneck in the development of investigational medicinal products, particularly biotechnological products.

Drug Development is Time-Consuming

Number of Compounds to Produce a New Drug

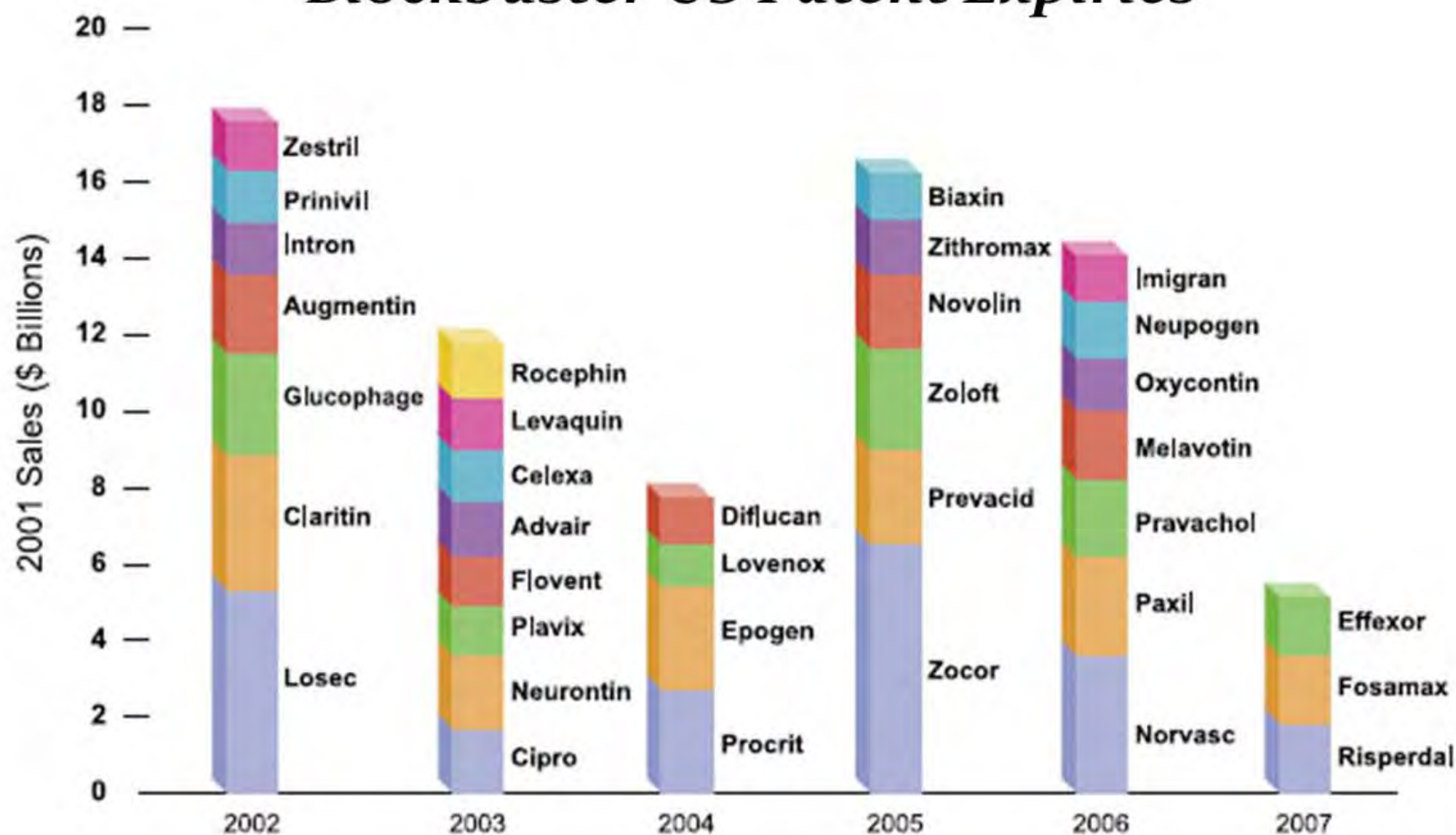


Source: PhRMA and FN estimates

10-15 years from start to launch

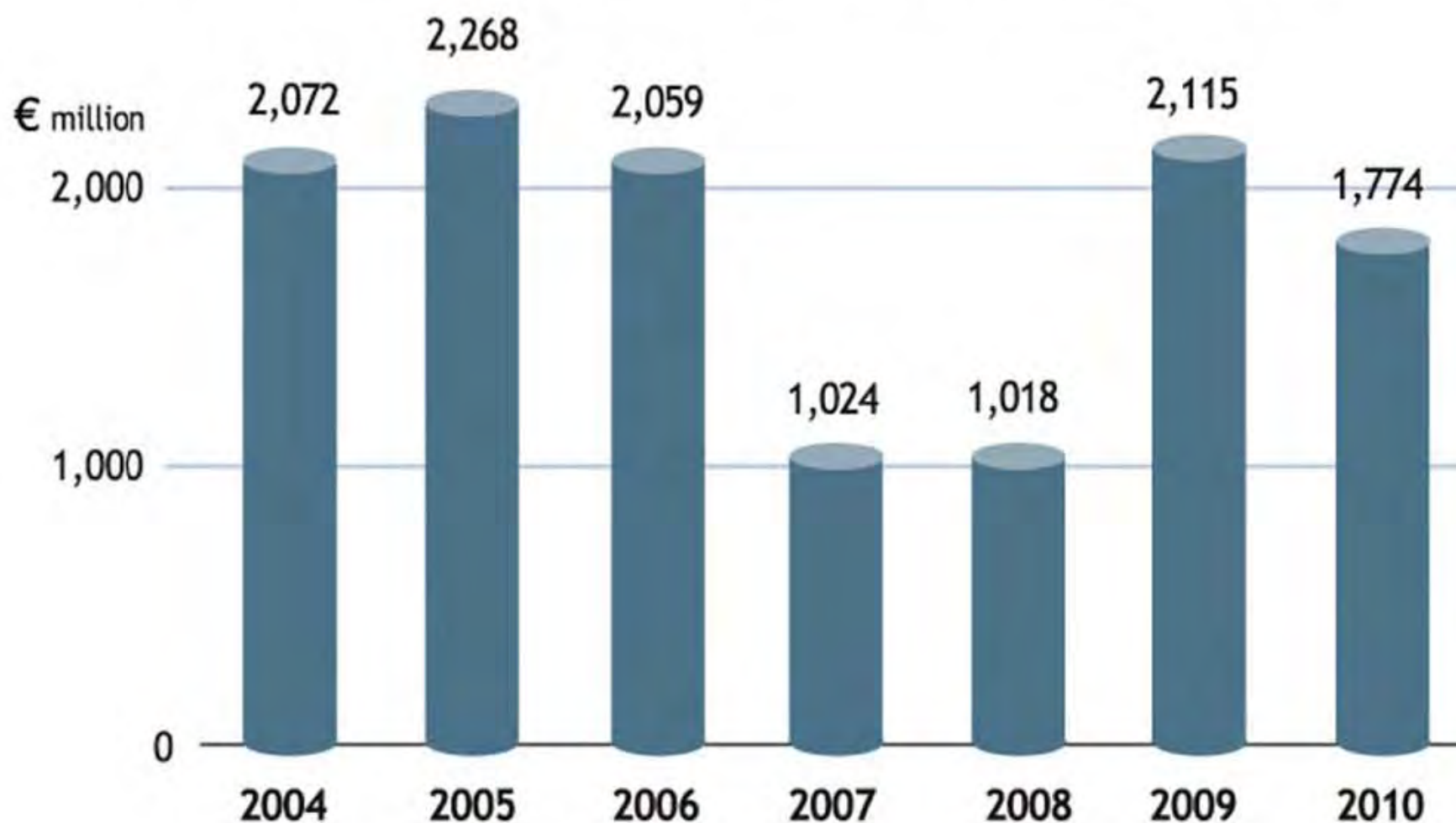
Drug Development: A Race Against Time

Blockbuster US Patent Expiries



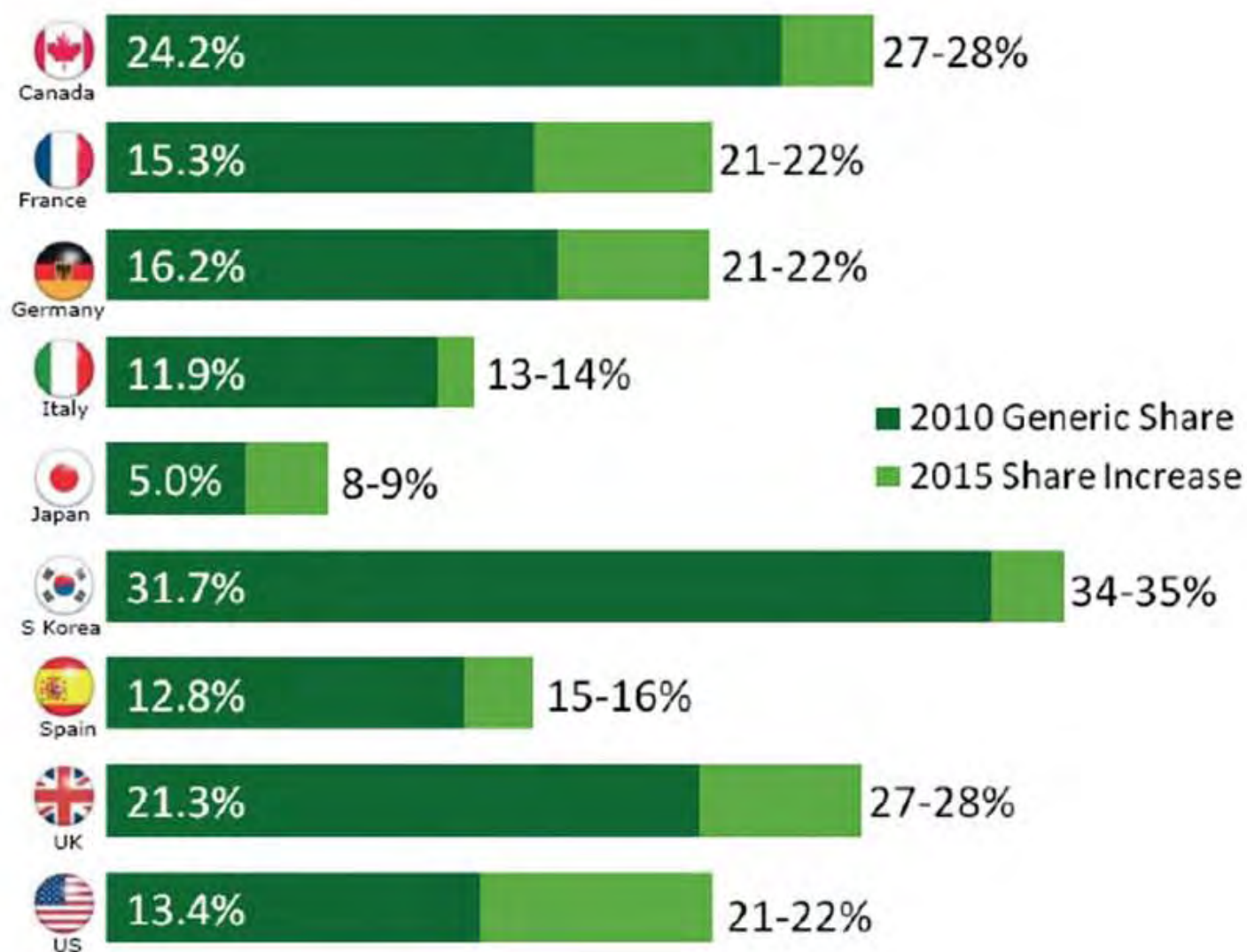
Drug Development: A Race Against Time

*Annual Sales Volume in the EU
becoming available for competition*



Drug Development: A Race Against Time

Developed Markets Generic Share



Source: IMS Market Prognosis, Apr 2011

Drug Development: A Race Against Time



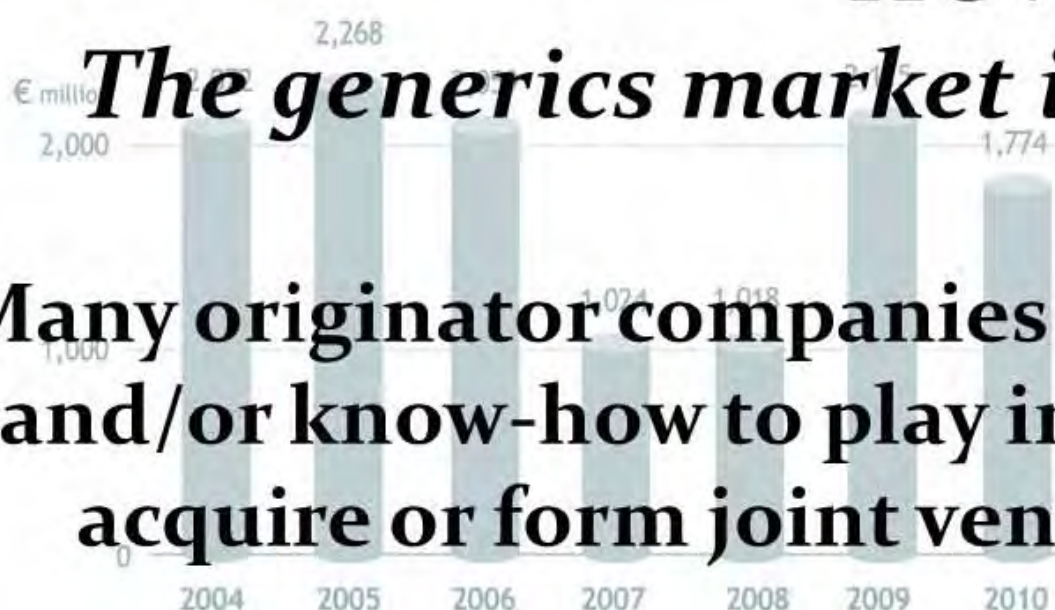
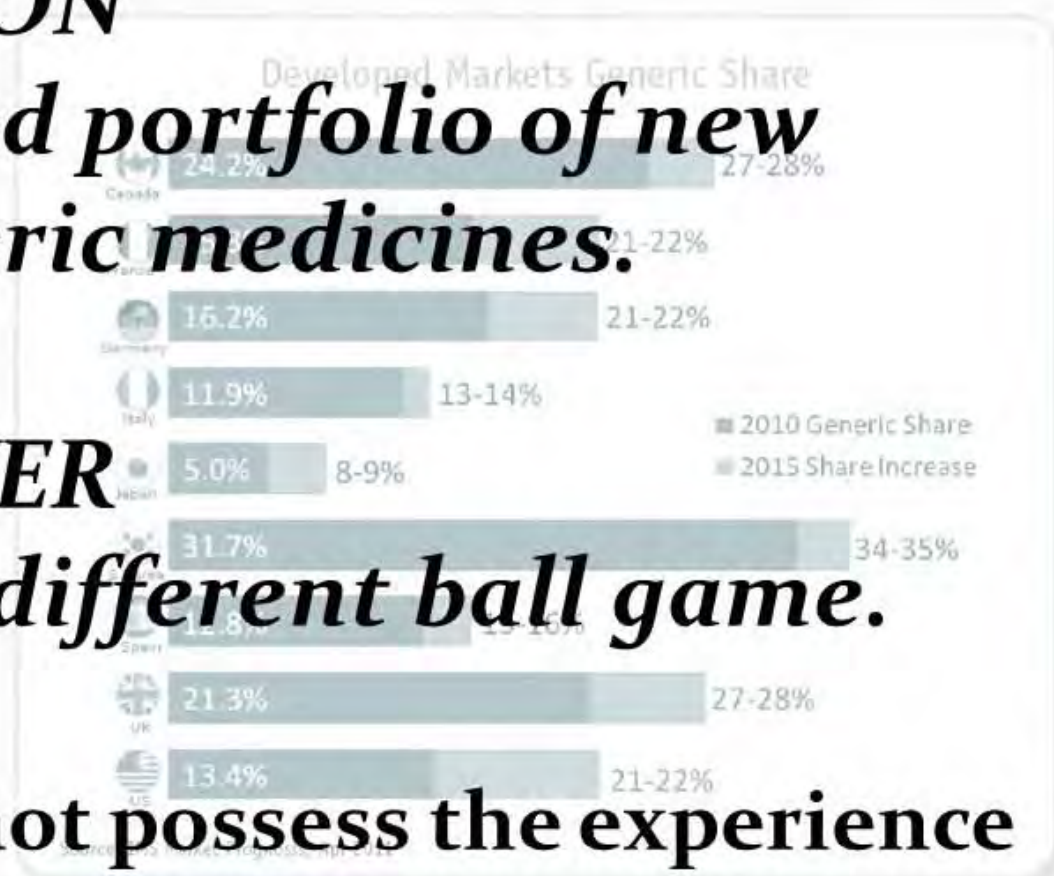
SOLUTION

Companies offer a mixed portfolio of new medicines and generic medicines.

HOWEVER

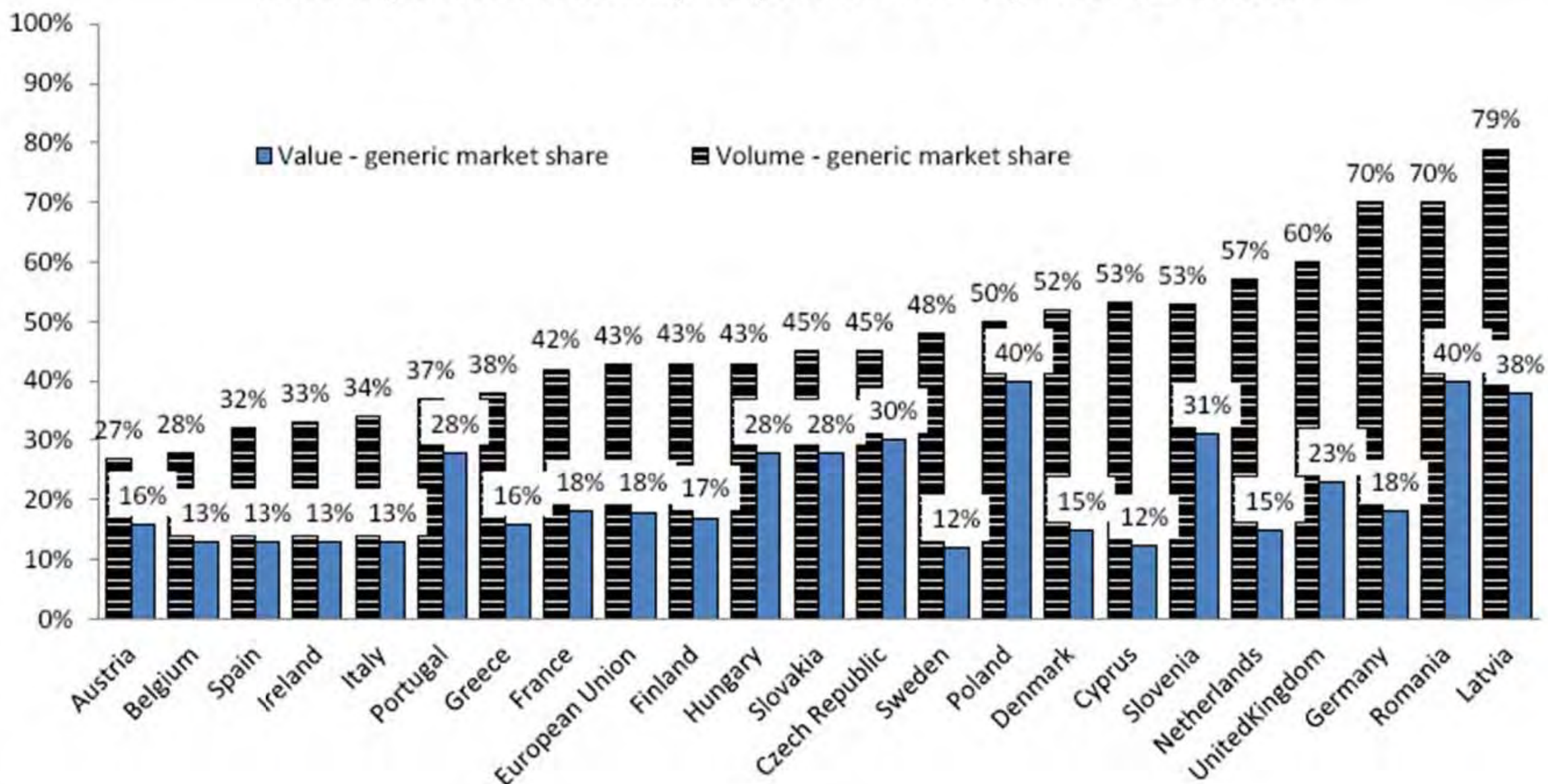
The generics market is a different ball game.

Many originator companies do not possess the experience and/or know-how to play in the generic space, and must acquire or form joint ventures with existing players.



Is Europe prepared to pay?

In Europe, generics make up almost one half of volume sales, but merely a fraction of value sales



Is Europe prepared to pay?

The European Union constantly considers cost-containment policies in public pharmaceutical spending.

- External reference pricing as a tool to control prices and set a parameter of expenditures.
- Rebates, clawback and payback policies.
- Internal reference pricing.

The inclusion of the most recent medicinal products in reimbursement lists or government formularies is sometimes inexplicably delayed.

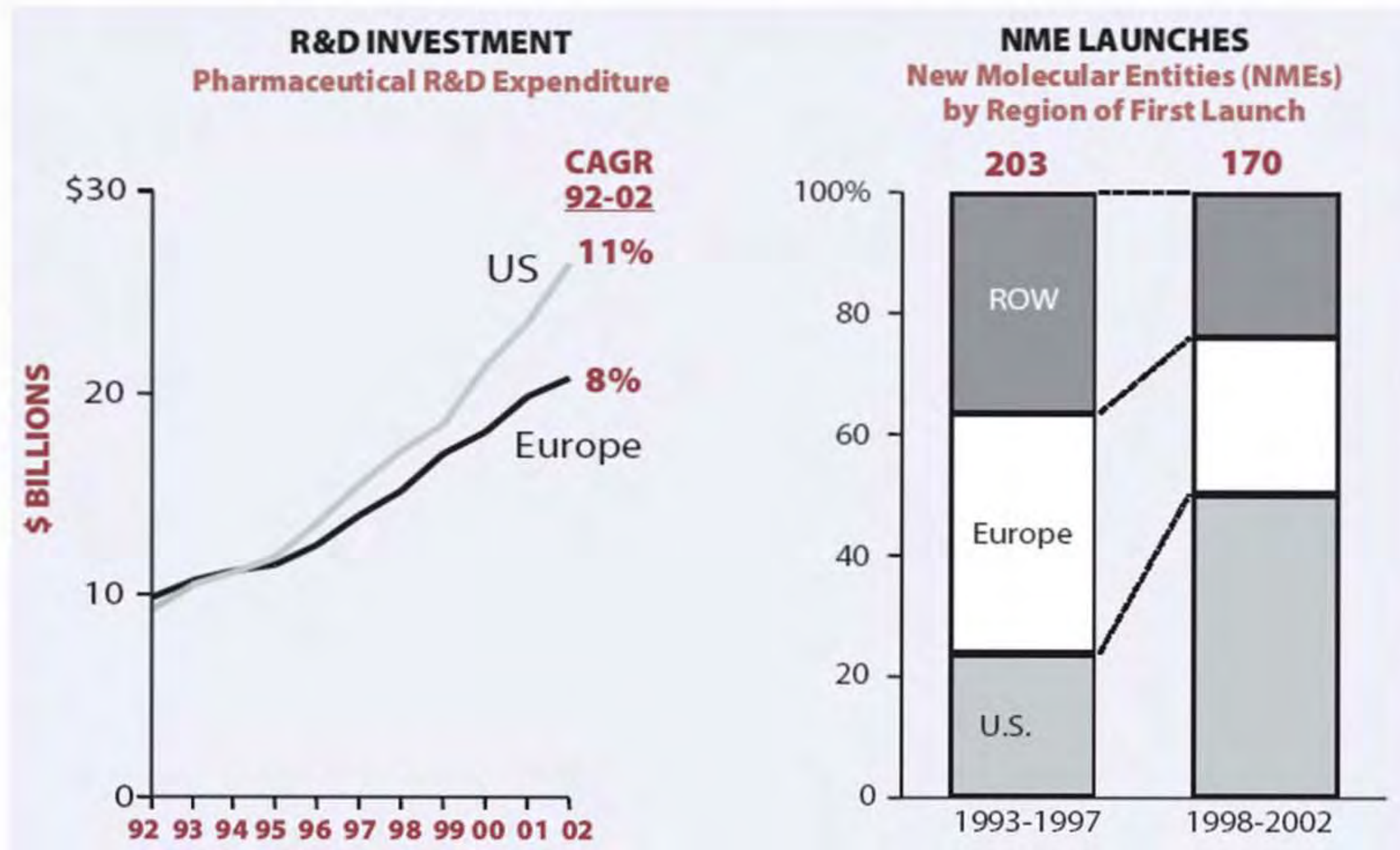
Is Europe prepared to pay?

“Europe has unfortunately slipped in terms of its willingness to pay for innovation. ... We’re now at a point where we have to take the view and I think face the reality that really it’s about the U.S. and, excitingly anew, it’s about Japan in terms of where innovation should be driven.”

(Sir Andrew Witty, CEO GlaxoSmithKline)



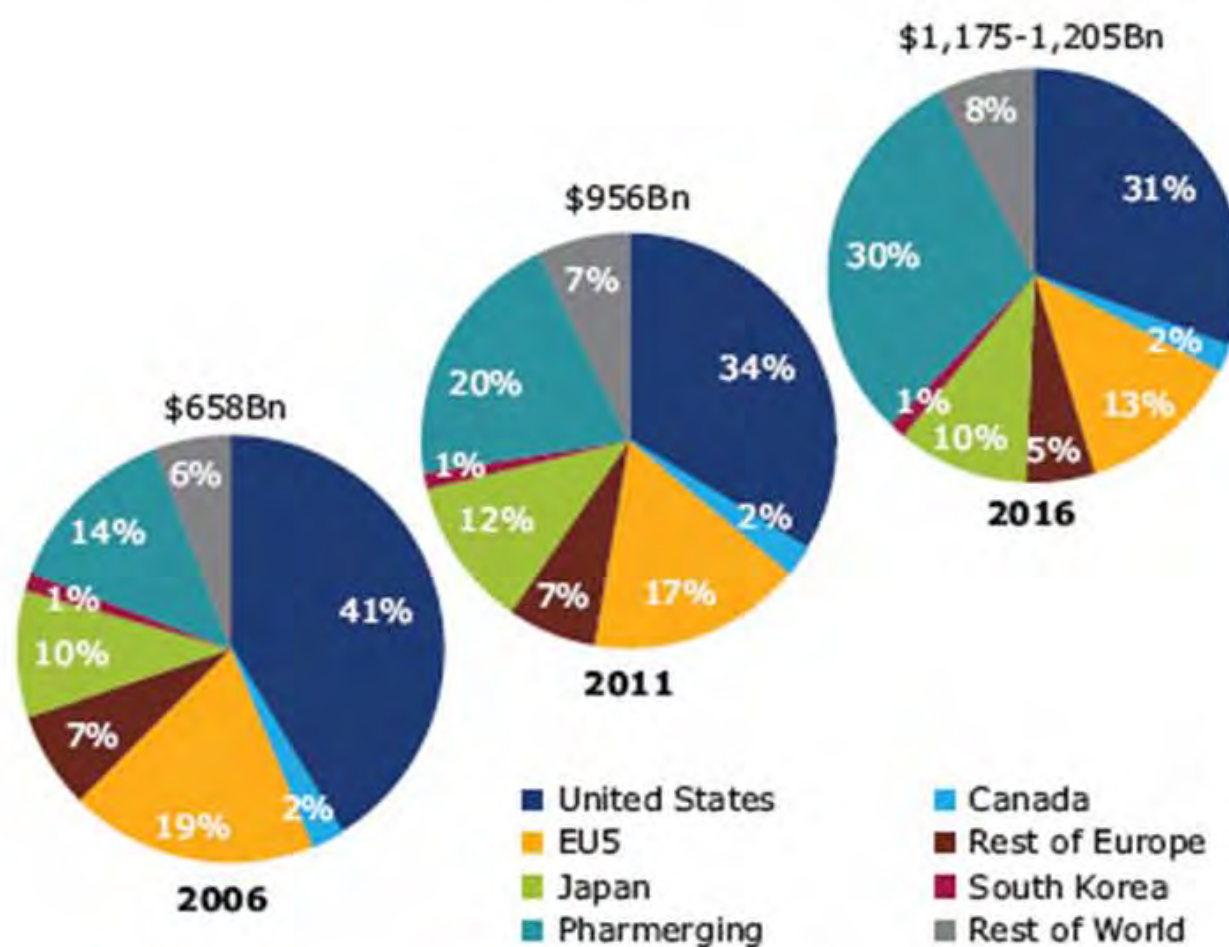
Where have we heard this before?



It's not quite déjà vu.

Enter the Pharmaemerging Markets

Spending by Geography



Source: IMS Market Prognosis, May 2012

It's not quite déjà vu.

Enter the Pharmaemerging Markets

RANK		2006	INDEX
1		United States	100
2		Japan	35
3	▲1	France	13
4	▼1	Germany	13
5	▲1	China	9
6	▼1	Italy	8
7	▲1	Spain	6
8	▼2	UK	6
9	▼2	Canada	6
10		Brazil	5
11		Australia	3
12		Mexico	3
13		South Korea	3
14		Russia	3
15	▼1	India	2
16	▲8	Turkey	2
17	▼2	Netherlands	2
18	▼2	Belgium	2
19	▲1	Greece	2
20	▼2	Poland	2

RANK		2011	INDEX
1		United States	100
2		Japan	36
3	▲2	China	21
4		Germany	14
5	▼2	France	12
6	▲4	Brazil	9
7	▼1	Italy	9
8	▼1	Spain	7
9		Canada	7
10	▼2	UK	7
11	▲3	Russia	5
12	▼1	Australia	4
13	▲2	India	4
14	▼1	South Korea	4
15	▼3	Mexico	3
16		Turkey	3
17	▲3	Poland	2
18	▲9	Venezuela	2
19	▼2	Netherlands	2
20	▼2	Belgium	2

RANK		2016	INDEX
1		United States	100
2	▲1	China	39
3	▼1	Japan	36
4	▲2	Brazil	15
5	▼1	Germany	13
6	▼1	France	11
7		Italy	8
8	▲5	India	7
9	▲2	Russia	7
10	▼1	Canada	6
11	▼1	UK	6
12	▼4	Spain	5
13	▼1	Australia	4
14	▲8	Argentina	4
15	▼1	South Korea	4
16	▼1	Mexico	3
17	▲1	Venezuela	3
18	▼2	Turkey	3
19	▲8	Indonesia	2
20	▼3	Poland	2

▼▲ Change in ranking over prior 5 years

Source: IMS Market Prognosis, May 2012

Appendix notes

Ranking in all years based on spending in constant US\$ at Q4 2011 exchange rates.

Index in each year based on ratio of country spending to U.S. spending (in constant US\$) in the year.

Outsourcing is not new

CHINA

Is becoming a key product-development center for General Electric, Intel, Philips, Microsoft, and other electronics giants. Strengths are hardware design and embedded software. Call centers for Japan and South Korea are growing in coastal cities.

PHILIPPINES

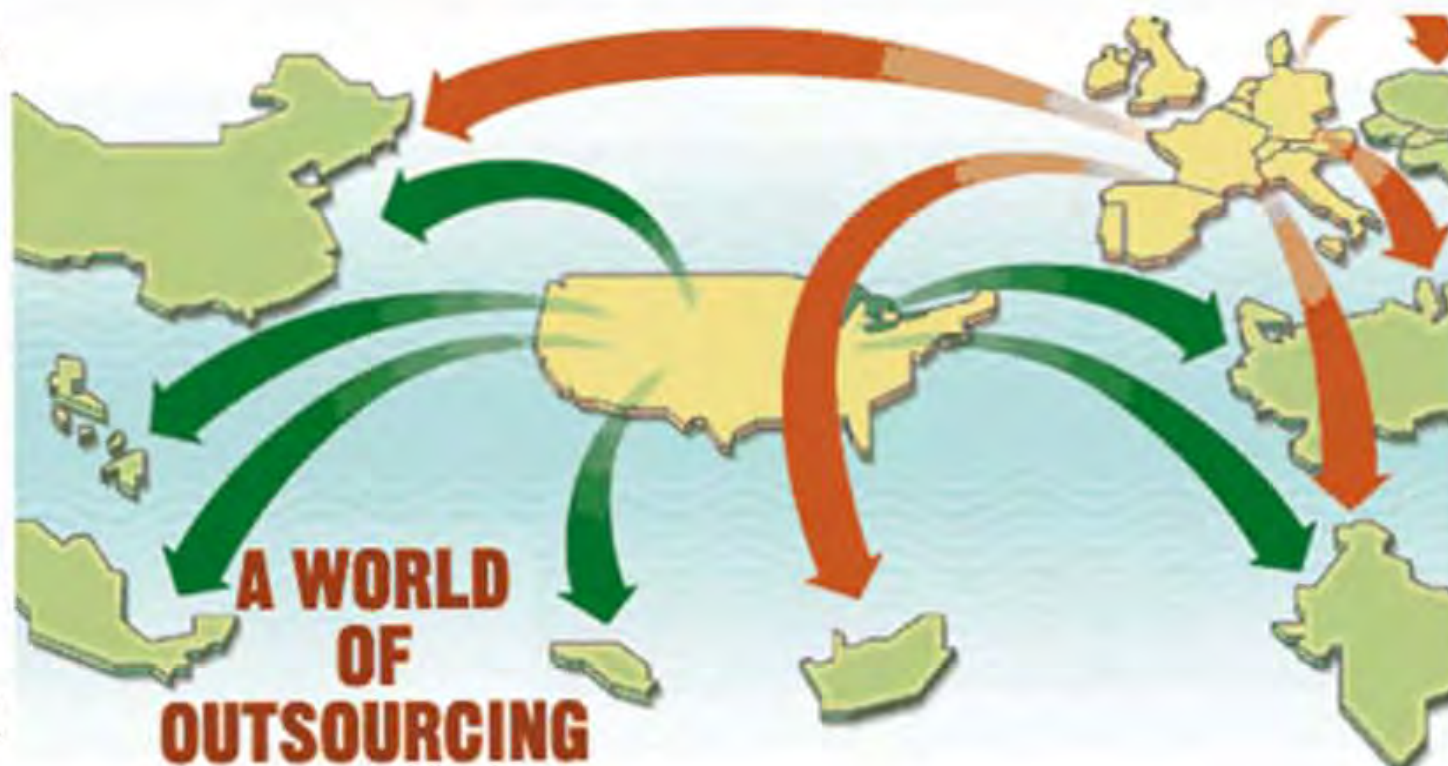
More than 8,000 foreign companies source work in nine different IT parks with fiber-optic links. Strengths include huge supply of English-speaking, college-educated accountants, software writers, architects, telemarketers, and graphic artists.

MEXICO

Becoming a favorite IT and engineering outsourcing haven for U.S. companies that want to keep work close to home. As car and electronics companies move manufacturing over the border, they are boosting demand for engineers.

COSTA RICA

Cheap telecom costs and educated workforce make San José a thriving spot for call centers targeting Spanish-speaking consumers in the U.S. and Europe.



SOUTH AFRICA

Well-educated speakers of French, English, and German from all over Africa staff growing call centers catering mainly to European companies. Deregulation of telecom could speed development. Other call centers are opening up in Mauritius.

EASTERN EUROPE

Indian and American IT service providers are opening offices in Hungary, Poland, and the Czech Republic to tap abundant German and English-speaking workforce for European clients. Romania and Bulgaria are growing as IT workshops for German multinationals.

RUSSIA

Some 100 local software service exporters employ up to 10,000 engineers specializing in complex projects. Boeing Nortel, Motorola, and Intel have small R&D centers. Still has an enormous untapped pool of master's and doctorates in sciences, IT, and math.

INDIA

IT services, chip design, call centers, and business back-office work already generate \$10 billion in exports and could hit \$57 billion by 2008. Indian providers like Tata, Infosys, and Wipro already are global leaders, and U.S. IT service firms are piling in.

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Made in Asia

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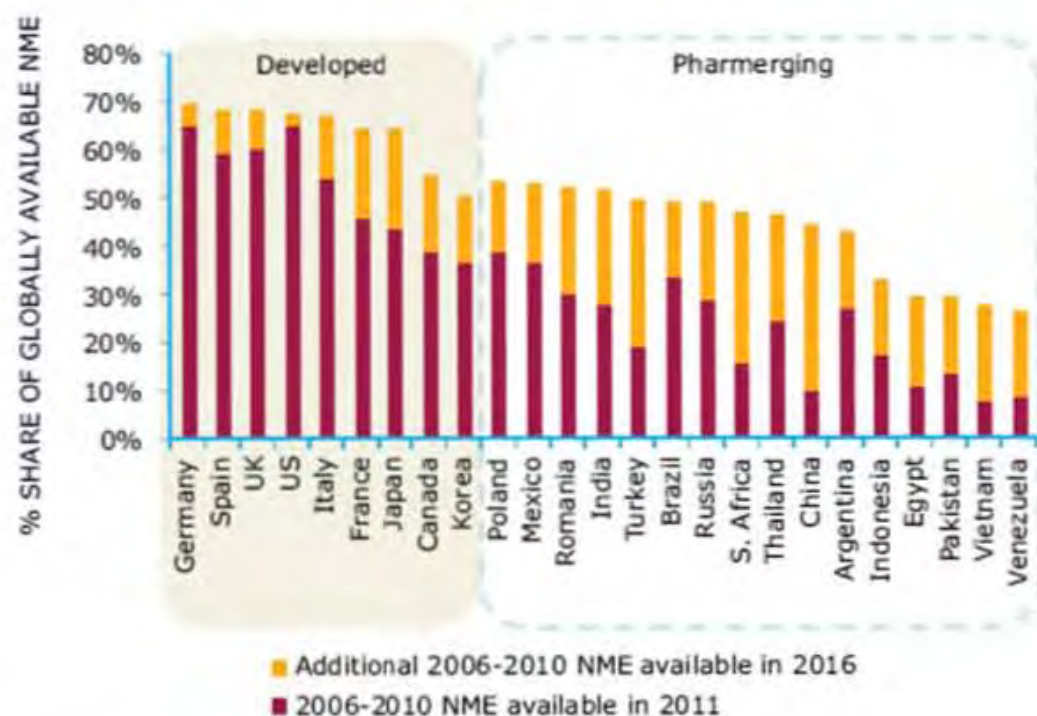
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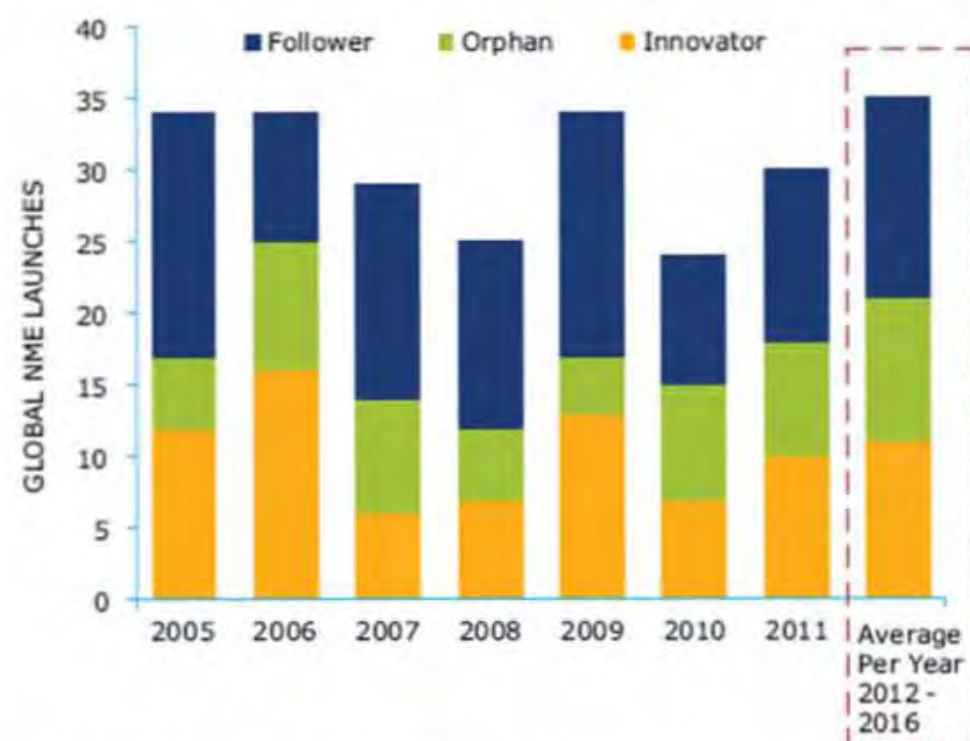
Are emerging markets the solution?

Global New Molecular Entities
Country Availability



Source: IMS Institute for Healthcare Informatics, May 2012

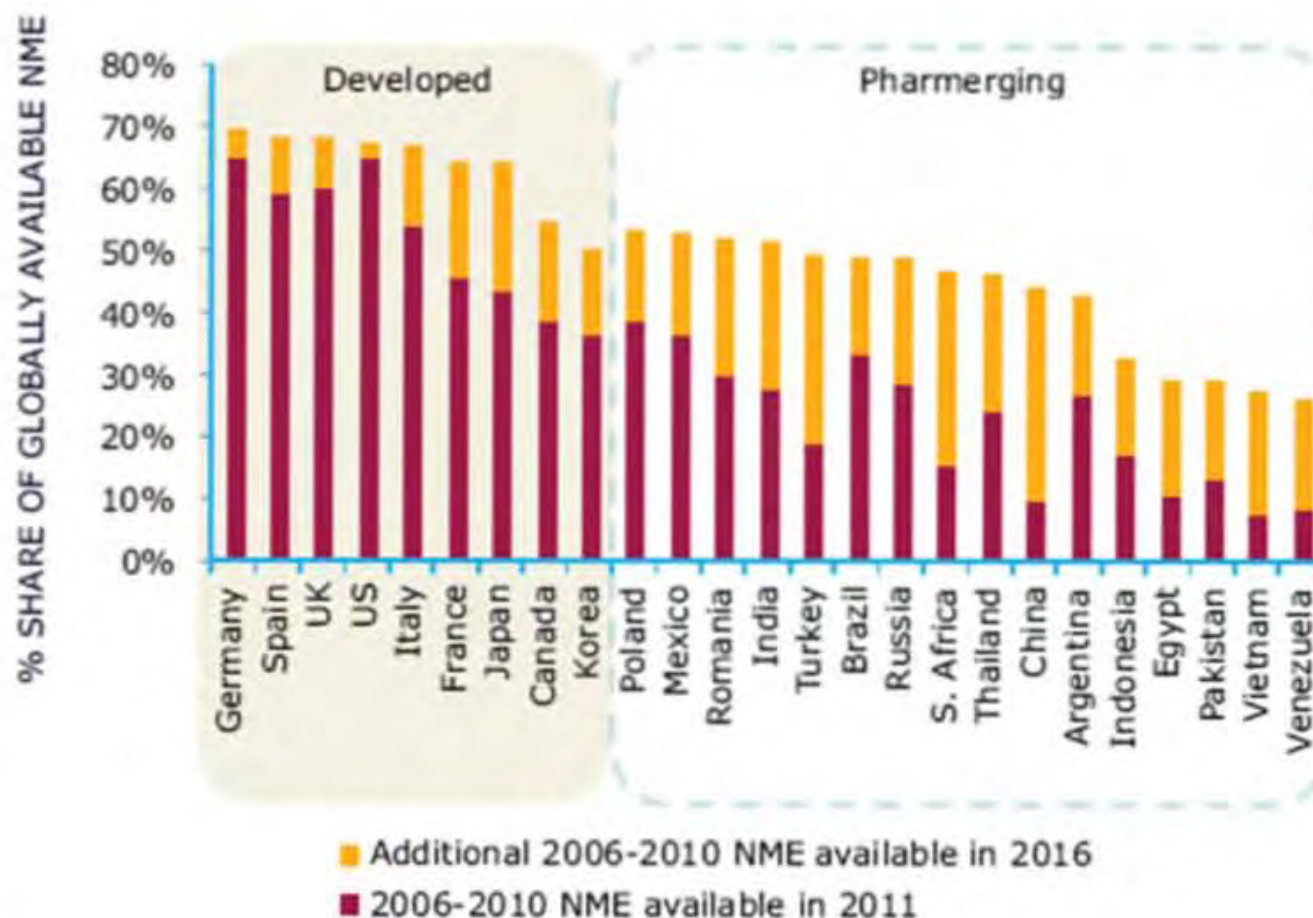
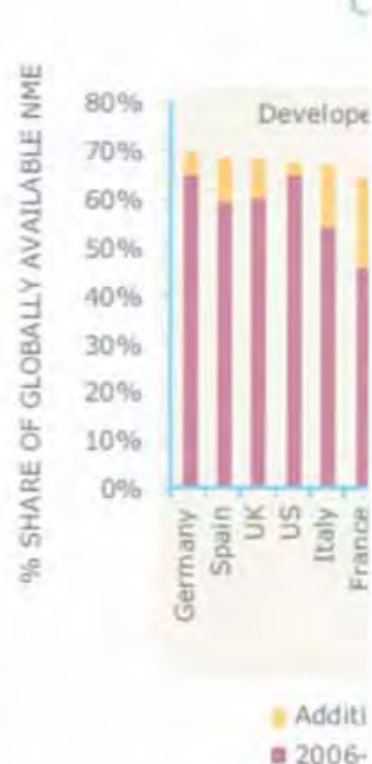
Global Launches of New Molecular Entities



Source: IMS Institute for Healthcare Informatics, May 2012

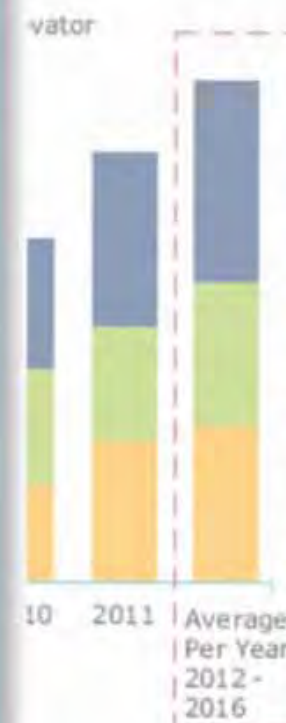
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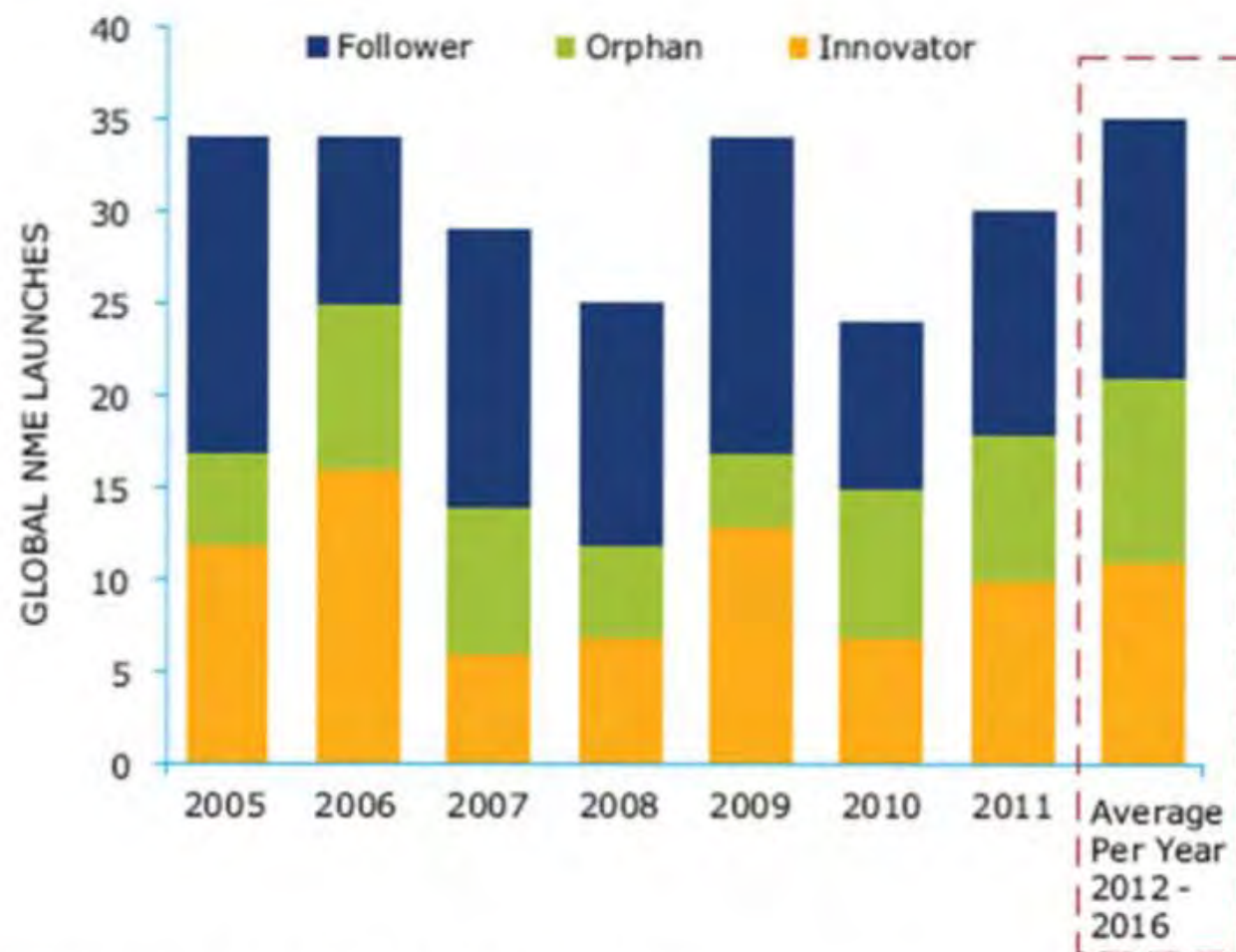


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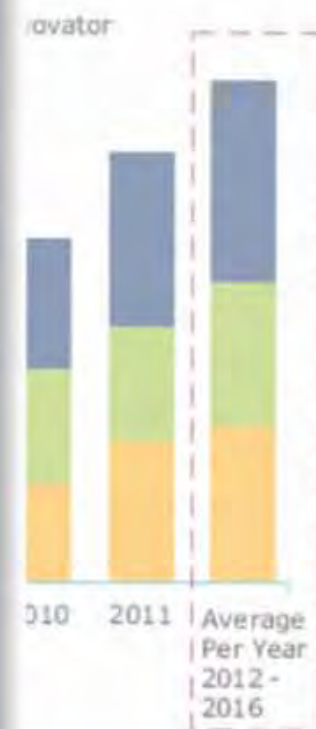
Global



Global Launches of New Molecular Entities



Molecular Entities



So let's access emerging markets

This is not as straightforward as it seems.

- Diverse healthcare systems
- Fragmented markets
- Complex regulatory systems
- Cultural and language barriers
- Increased competition (local and global)
- Varied infrastructure
- Highly dynamic situation

India: A case study

In 2005:

- Sector ranked 4th worldwide in volume terms, 13th in value.
- Market worth €3.6 billion (1% of world market in value, 8% in volume).
- Growth rate of 5.1%, projected to reach €18.8 billion by 2010.
- Total exports around €2.25 billion, to over 65 countries.

India: A case study

Why this success?

Jugaad: Literally, an arrangement or a workaround, which has to be used because of lack of resources. Practically, a creative idea, a quick, alternate way of solving or fixing problems.



India: A case study

Today:

- Plans to widen scope of price controls to 348 medicines from the current 74. *“Most countries follow some form of price control. We need to ensure that expensive drugs are available at affordable rates to the poor.”*

(D.S. Kalba, Secretary, Pharmaceutical Department)

India: A case study

Figure 2: The Wealth Pyramid across the emerging markets (adapted from Prahalad and Lieberthal, 1998).

Purchasing power parity		Population in millions		
	In U.S. dollars	China	India	Brazil
Have a lot	Greater than \$20,000	2	7	9
Have	\$10,000 to \$20,000	60	63	15
Have less	\$5,000 to \$10,000	330	125	27
Have not	Less than \$5,000	800	700	105

India: A case study

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- Big Pharma is having a hard time protecting the intellectual property of its anticancer drugs.

India: A case study

“The danger of pushing the prices of prescription drugs down, down, down is that at some point the business model of developing these drugs will lose its attractiveness. India is becoming very reluctant to respect IP for Western companies and that is becoming a challenge for us.”

(Marijn Dekkers, CEO Bayer)



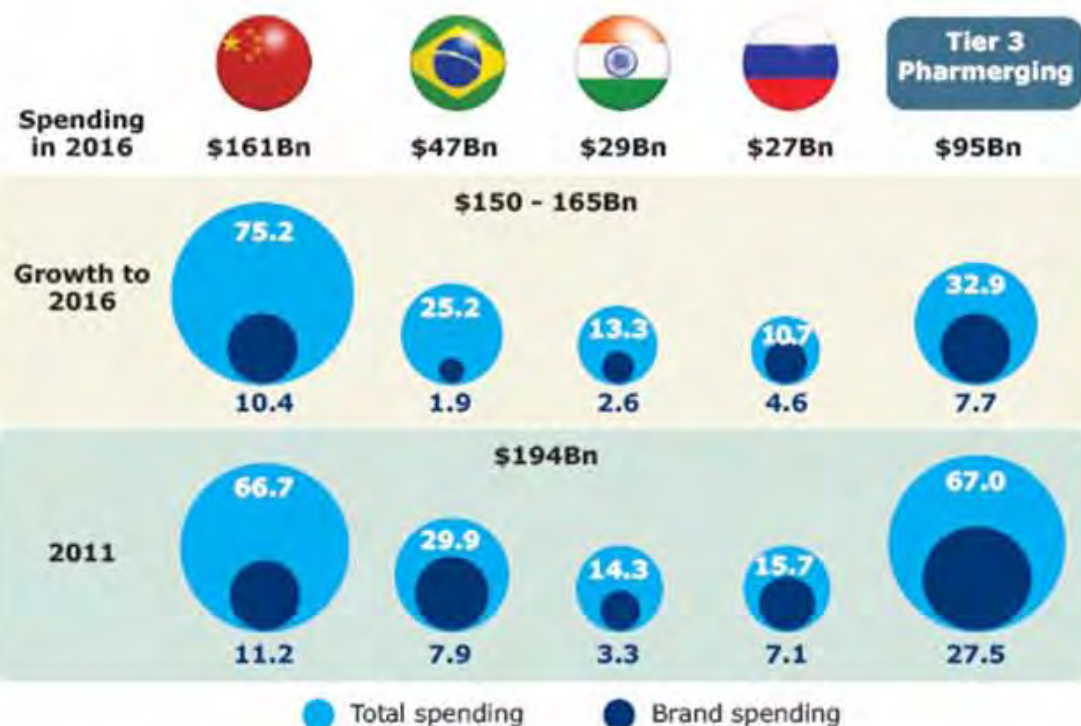
Is the writing on the wall?

If it seems too good to be true,

It probably is.

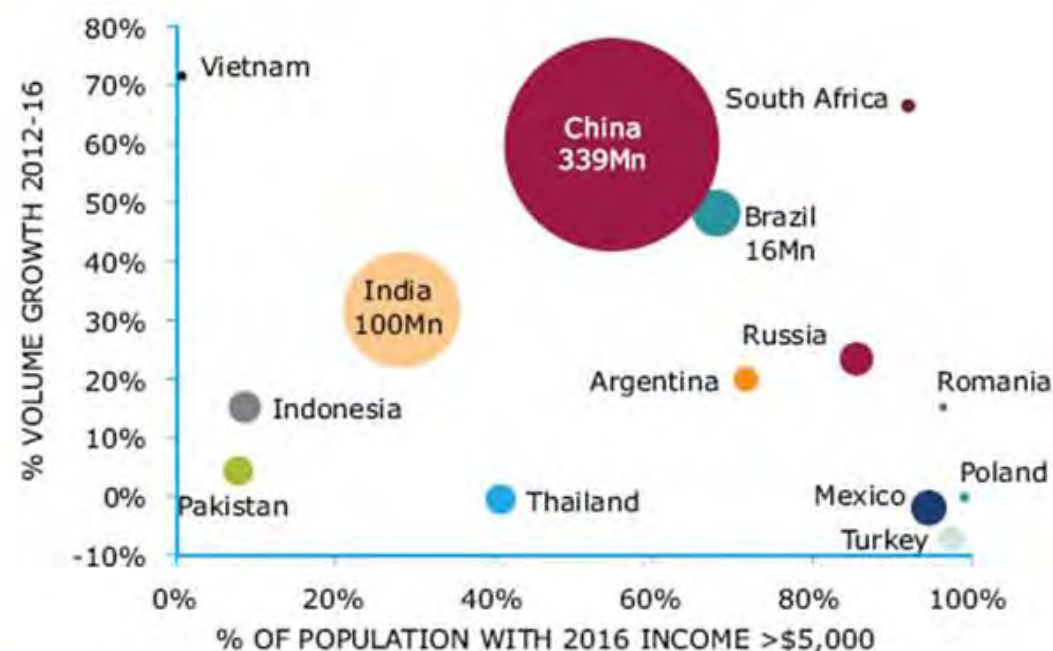
Is the writing on the wall?

Pharmerging Spending and Growth



Source: IMS Institute for Healthcare Informatics, IMS Market Prognosis, May 2012

Volume Growth and Populations With >\$5,000/Year Income by Country in 2016



Source: Institute for Healthcare Informatics, IMS Market Prognosis, May 2012; Economist Intelligence Unit, Jan 2012

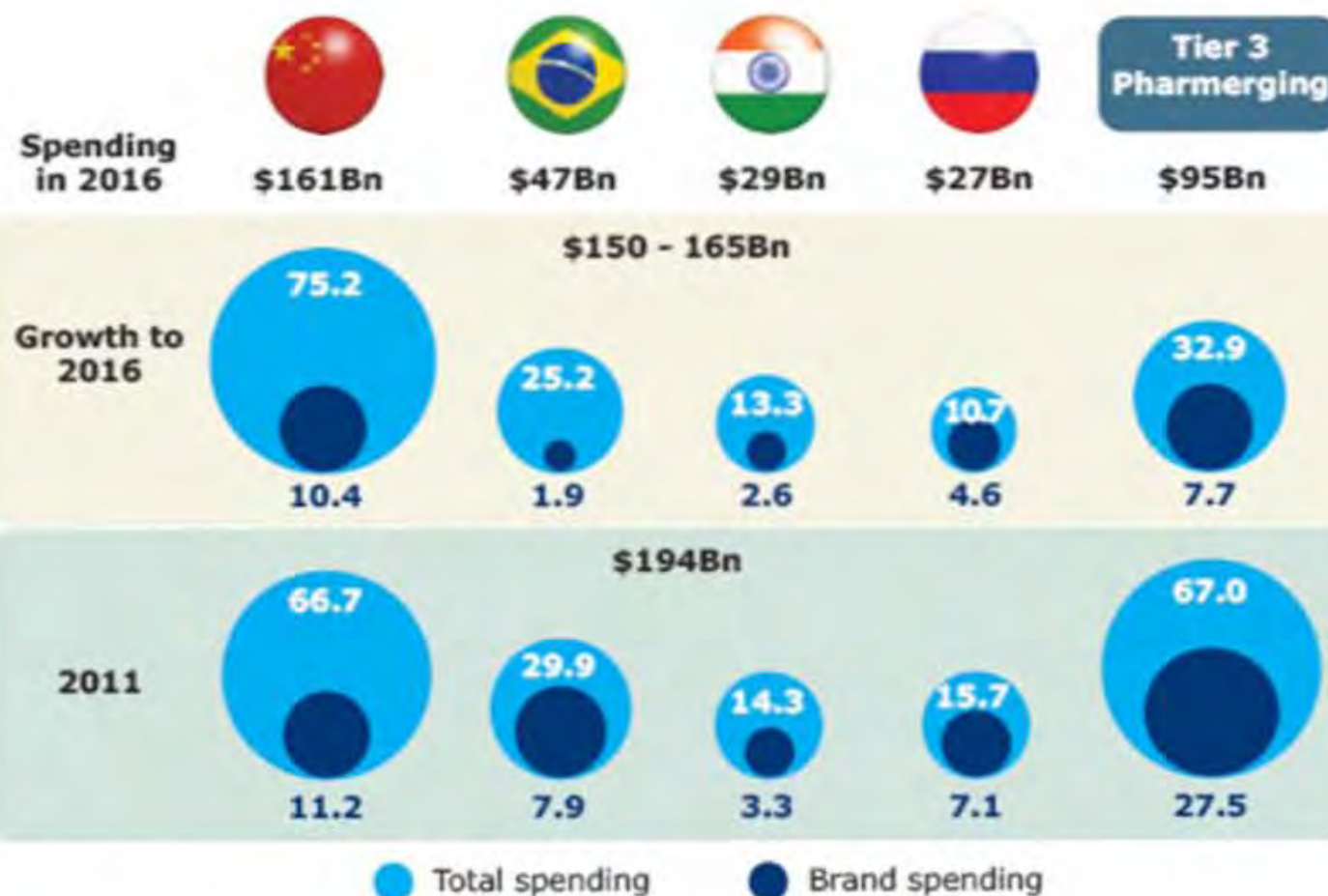
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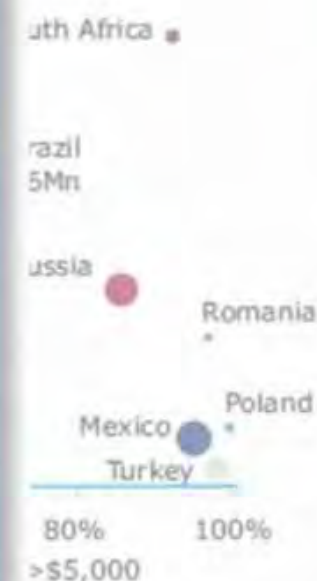
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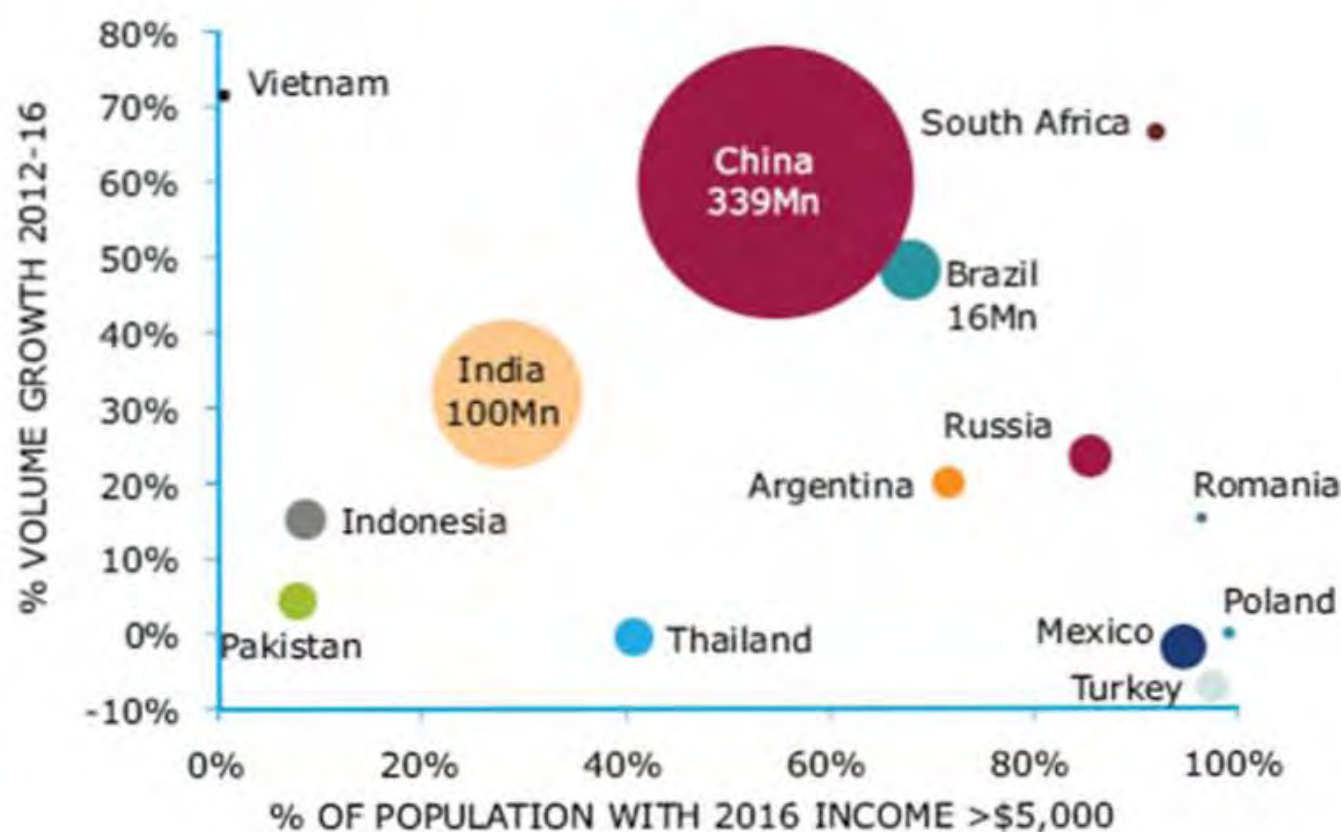
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Pharmaceutical



Source: IMS Institute for Healthcare I

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Populations
Country in 2016



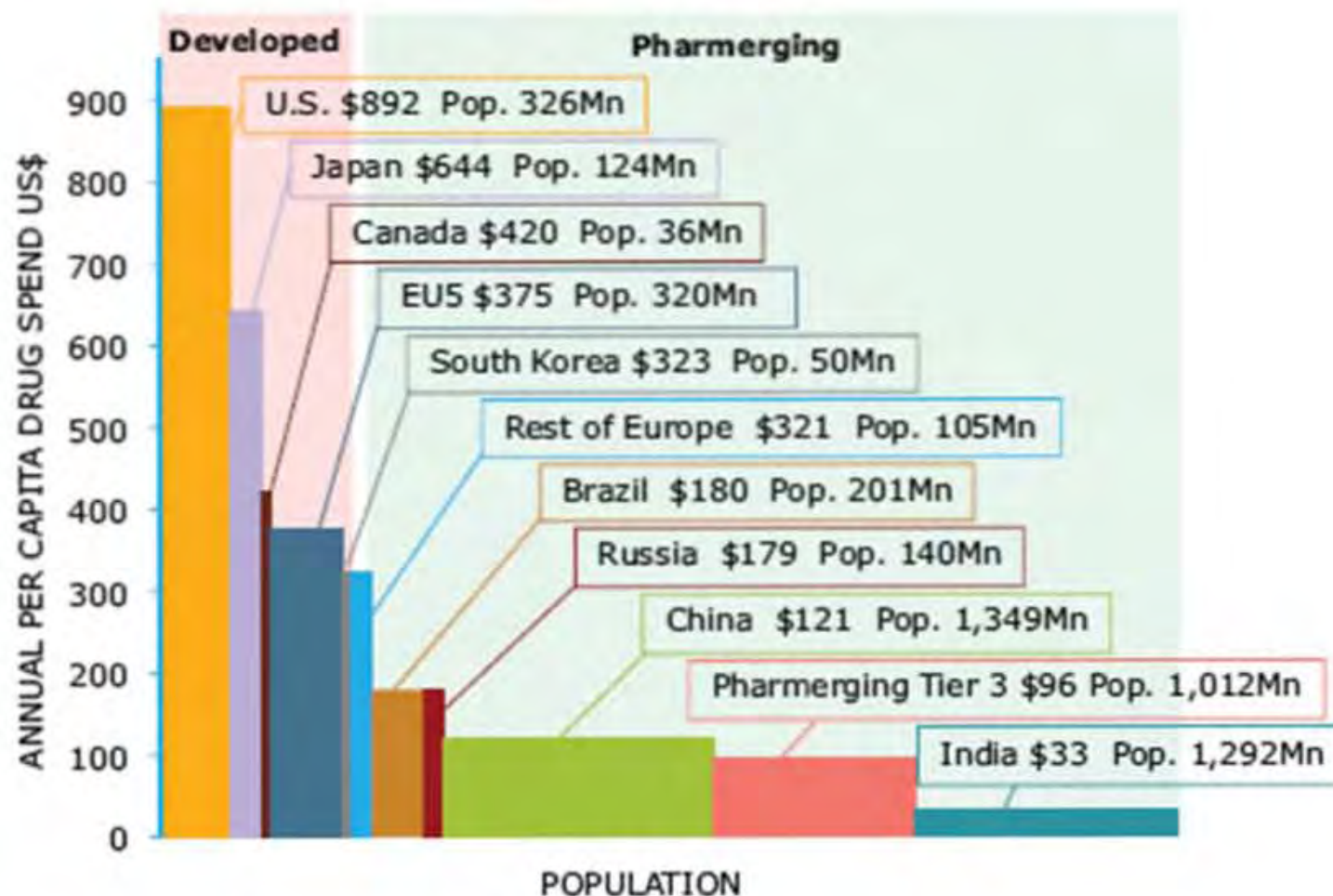
Source: Economist Intelligence Unit, Jan 2012

Challenges in Emerging Markets

- Many companies struggle with regulatory standards in different global regions; companies from certain regions may work to higher standards than FDA or EU GMP.
- Pricing products is problematic. Different systems exist and reference pricing lists change regularly. The wrong decision in one market can backfire in an another region. NICE-like systems are being established in emerging markets.
- Products from certain countries are not easily registered in other countries due to historical and cultural issues.
- Wealth Pyramid is unlikely to change and generates different attitudes towards intellectual property protection: counterfeiting activities follow pharma in emerging markets.

Challenges in Emerging Markets

2016 Pharmaceutical Spend Per Capita
2005\$ and Population



Source: IMS Market Prognosis, May 2012; Economist Intelligence Unit, Jan 2012

Falsified Medicinal Products

	2008	2009	2010	2011
Number of cases	3,207	3,368	1,812	2,494
Number of articles	8,891,056	11,462,533	3,200,492	27,460,538
Provenance Top 3	India (51.6%)	UAE (73.7%)	India (93.2%)	China (68.2%)
	Syria (36.4%)	India (22.6%)	China (4.7%)	India (28.2%)
	UAE (8.7%)	China (1.4%)	Hong Kong (0.9%)	Hong Kong (1.5%)

European Commission Taxation and Customs Union

Quality and safety are non-negotiable

- Manufacturer will remain responsible for ensuring EU GMP compliance of the API manufacturers he uses. Applicant for MA must confirm in writing that manufacturer of finished product has verified compliance with EU GMP of API manufacturer through audits.
- Finished product manufacturer must ensure that APIs it uses have been manufactured in line with EU GMP & distributed in line with EU GDP by conducting audits.
- Onus is on Qualified Persons.

Quality and safety are non-negotiable

- Medicinal products to bear safety features enabling whole distributors and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product and identify individual packs, as well as a device allowing verification of whether the outer packaging has been tampered with.
- Qualified Person has to ensure that the safety features have been affixed on the packaging.

Changes in the industry: globalisation

- Local knowledge is the key to working locally, but how is this knowledge integrated with the rest of the corporation?
- Change agents whose focus is emerging markets are needed throughout the organisation to provide the missing link.



SCOTTISH HIGHLANDS
Lucky



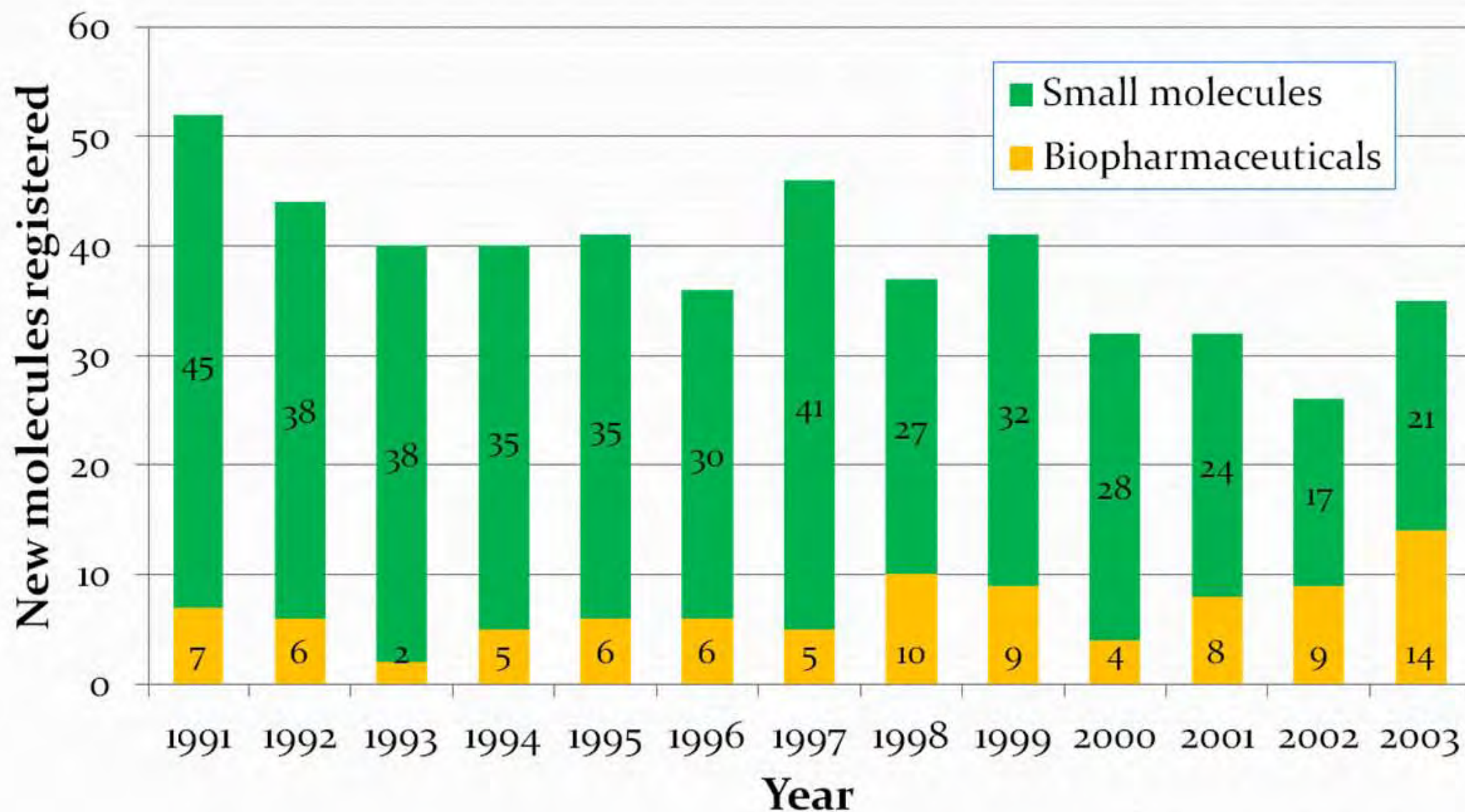
NORTHERN VIETNAM
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Never underestimate the importance of local knowledge.

Flowers mean different things the world over and to understand those differences, it helps to be a local. At HSBC, we have banks in more countries than anyone else. And each one is staffed by local people. We have offices in 77 countries and territories: Europe, Asia-Pacific, the Americas, the Middle East, and Africa. Being local enables them to offer insights into financial opportunities and create service initiatives that would never occur to an outsider. It means our customers get the kind of local knowledge and personal service that you'd expect of a local bank. And a level of global knowledge and widely sourced expertise that you wouldn't.

HSBC 
The world's local bank

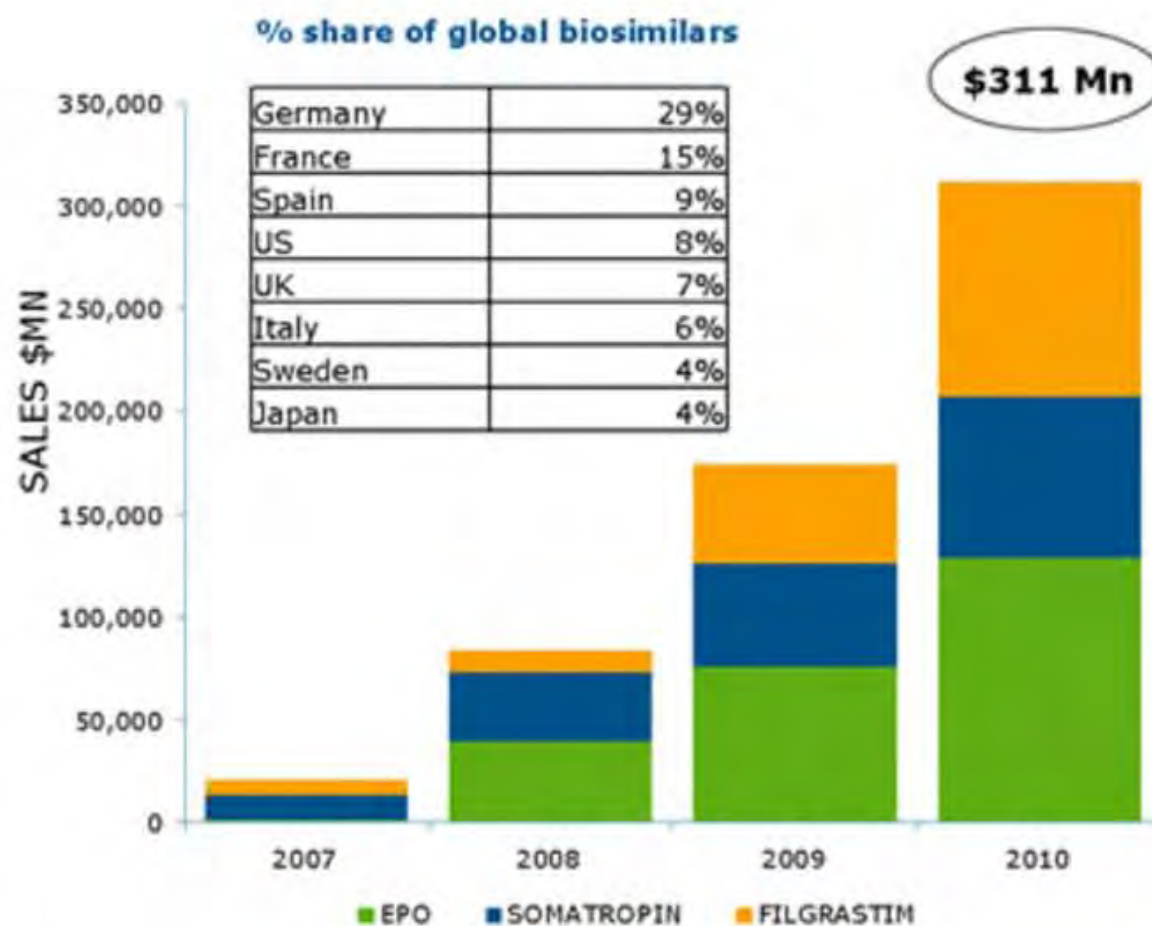
Changes in the industry: biologicals



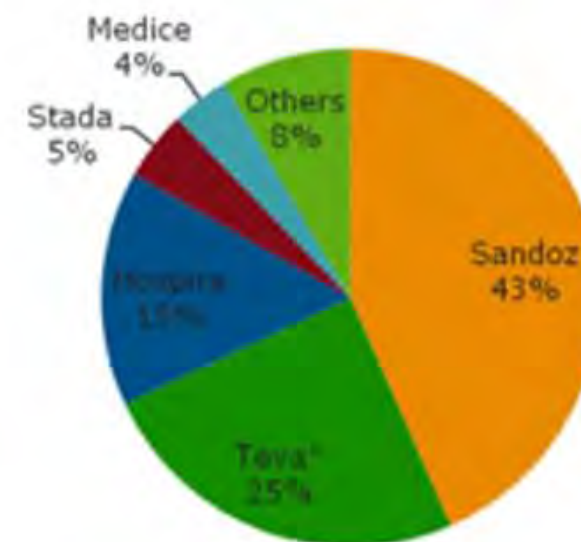
Changes in the industry: biologicals

Biosimilar penetration in Europe embryonic;
potential in USA post 2014

For R&D based companies is going to be an established market play



Biosimilars: Top players (US\$)



Source: IMS Health, MIDAS, MAT Dec 2010; USA (Omnitrope) + Europe + Australia. *Teva = Teva + Ratiopharm

The industrial pharmacist of the future

Seven Skill Sets Necessary to Operate in the Pharmaceutical Industry of the Future

- 1) Ability to Manage Decentralized Intellectual Capital Resources
- 2) Ability to Work in Joint Ventures and Across Divisions, Cultures and Countries
- 3) Ability to Integrate an Understanding of Intellectual Property Laws, Scientific Expertise and Business Strategy
- 4) Ability to Spur Creativity While Managing Commercially
- 5) Knowledge and Insight on the Decision-Making Dynamics of Payers
- 6) Expertise in the Functioning and Decision-Making of Regulatory Agencies
- 7) Human Resource Skills to Help Transform Pharmaceutical Companies

The industrial pharmacist of the future

- ***A changing workplace:***
 - drug discovery in Europe with drug development conducted in India and registration executed in Europe or North America
 - drug discovery occurring in China, developed in China, commercialised in China and then registered and commercialised in Europe
 - drug discovery conducted in China, development conducted in India and commercialised in Europe
- Basic Formulation Development for small molecules will be outsourced to low cost countries whereas large molecules will be developed in the EU and USA.



European Industrial Pharmacists Group

- The main objective of EIPG is to promote and uphold the importance and role of the industrial pharmacist within the pharmaceutical industry.
 - Promote the modern pharmaceutical industry to observers and more importantly to young pharmacists
 - Ensure that educational standards meet the needs of the industrial pharmacist in the industry of 2020
 - Provide mentoring and coaching to young pharmacists who need career advice



European Industrial Pharmacists Group

- However, the industrial pharmacist of the future needs to evolve with the industry in which he/she operates.
- The industrial pharmacist of the future needs to think differently.
- The industrial pharmacist of the future needs

Jugaad