

# Do We Need Medical Affairs?

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# Biographical Sketch of Dr Richard Nieman



- Dr Richard Nieman, MB BS FRCP is Vice President and Head of Medical Affairs, Asia at Bayer Healthcare Pharmaceuticals. Richard is based at Bayer's Global R&D center in Beijing, China and is responsible for leading Bayer's medical organization in China, Japan and the countries of the Asia-Pacific Region.
- Richard qualified in medicine and trained as a pulmonologist in London, UK at St. Mary's Hospital and the Royal Brompton National Heart and Lung Institute. He has substantial experience in respiratory and anti-infective drug development and commercialization from prior clinical development and medical affairs roles in Europe and the USA at GSK, Aventis and Schering-Plough. Richard joined the Bayer group in 2006 and has held a number of key roles in Global Development, including US Medical Director, and Head of Global Medical Affairs Therapeutic Areas where he was responsible for the medical activity for all key global brands.
- Immediately before joining the pharmaceutical industry, Richard spent two years as a clinical research fellow in the Department of Thoracic Medicine at the National Heart and Lung Institute, London UK researching cystic fibrosis. He holds several patents related to novel drug development, and was the senior author on a New England Journal of Medicine publication related to asthma and antibiotics. In 2009, Richard was honored by being elected as a Fellow of the Royal College of Physicians (UK) for his contributions to pharmaceutical medicine.

# Do We Need Medical Affairs?



- Yes?
- No?
- Maybe – not sure?
- Sometimes?
- **More than ever?**

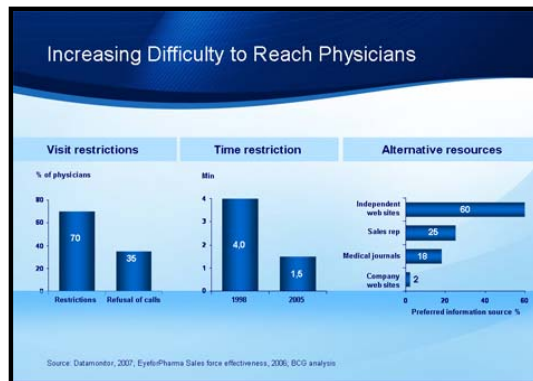
# The Pharmaceutical Industry is Changing



## Global R&D productivity is falling



## The commercialization of products is changing



**Continued pressure to manage profitable growth**

## Pricing & Reimbursement are becoming more difficult



## Growth opportunities in "pharmerging" markets

Increasing Importance of Emerging Markets

Country	2006 market size in \$ billions	Incremental growth 2006-15 in \$ billions	2006-15 CAGR in Percent
China	31	49	11
Japan	108	31	3
Russia	14	28	13
Brazil	25	25	8
India	13	23	12
U.K.	39	22	5
France	51	21	4
Germany	54	16	3
Italy	34	12	3
Spain	25	12	4

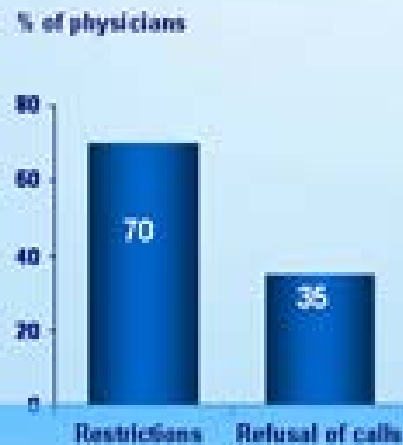
\*Health Care products include pharmaceuticals, consumer products and medical devices, and diagnostics  
Source: India Pharma 2015, IMS; Nicholas Hill; Datamonitor; Eisgcom; Eurcombar; interviews; team analysis

# Novel Ways are Needed to Interact with Physicians

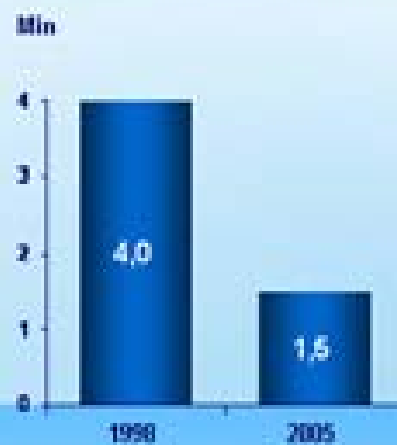


## Increasing Difficulty to Reach Physicians

### Visit restrictions



### Time restriction



### Alternative resources



Source: Datamonitor, 2007; EyeForPharma Sales force effectiveness, 2006; BCG analysis

# And Organizations Will Need New Skills...



## Situation in 2000

- A product with equivalency data will get approved and reimbursed
- No major criticism of industry
- No medicomarketing or compliance codes
- Few if any government audits
- Easy access to physicians
- Relationship component relevant

## Situation in 2011

- Robust Safety, efficacy and value data are essential
- Negotiations with government and other stakeholders critical for pricing/reimbursement
- Industry behavior under scrutiny
- Evolving, stringent and complex codes
- Regular audits
- Access to physicians not as easy
- Resource constraints
- New digital channels evolve

## New Skills

- Understand HEOR/Access
- Know how to negotiate with government and other new stakeholders
- Good knowledge of key clinical studies relating to own and competitor products
- Improve media awareness and ability to present industry issues to media
- Participate to influence codes, improve legal understanding
- Increase launch and commercial effectiveness
- Knowledge of how to use digital and other new channels
- Achieve growth despite cost efficiencies

# The Scope of Medical Affairs has Changed



- **Core Medical Affairs Activities**
- Support for development studies and regulatory activities
- Phase IV studies
- ISS programs
- Advisory boards
- Medical information
- Scientific communications
- KOL advocacy development
- Review of promotional material
- Medical Governance
- Critical Issue Management

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## • Newer Areas for Medical Affairs

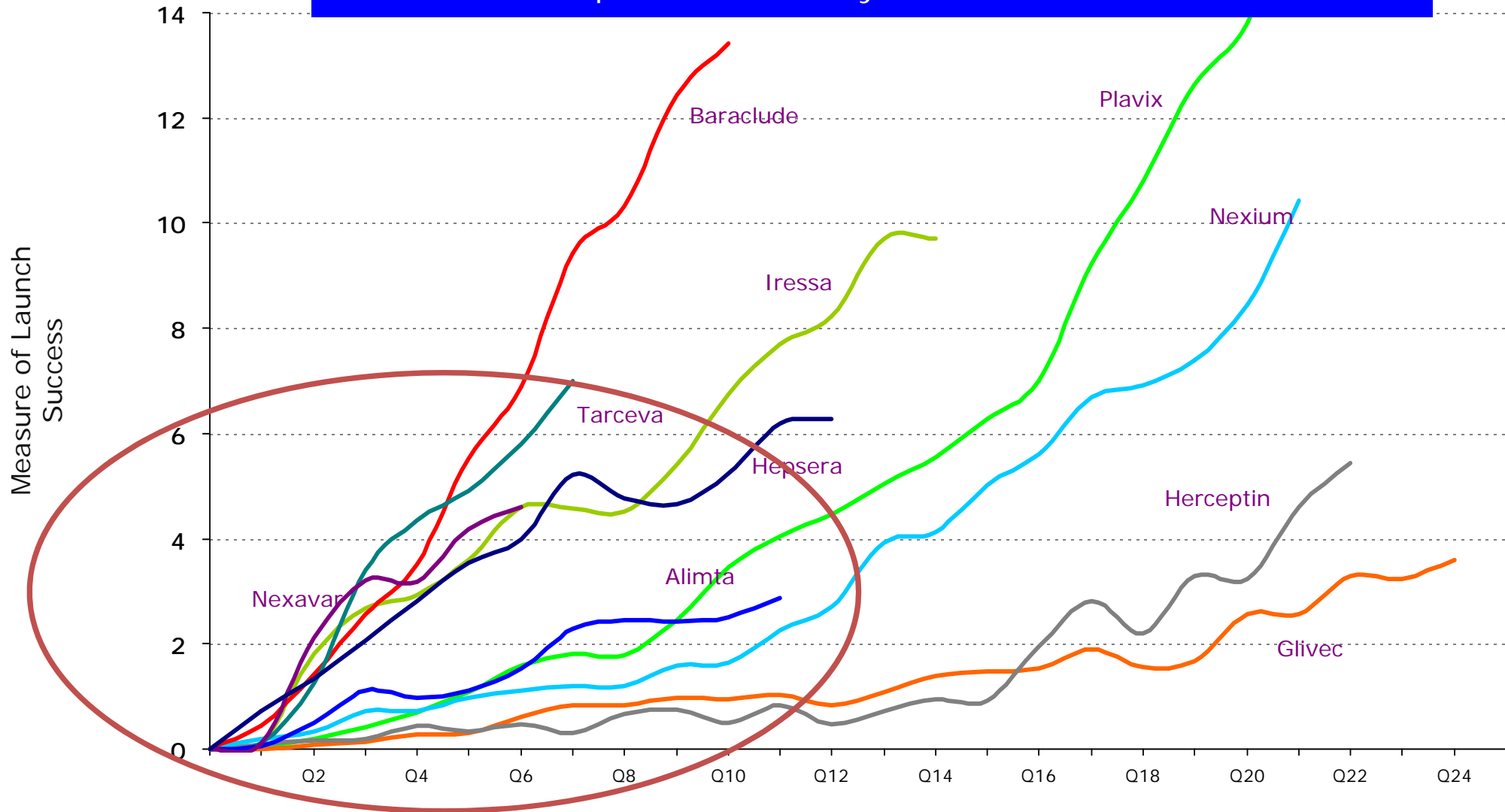
- EBM and Value propositions
- Credibility with key influencers and customers
  - Access and share of voice through peer-to-peer communication (MSLs)
- Medical input to shape product strategy
- Epidemiology and risk-management
- Insights into patient behaviors and customer channels
- Scientific and medical platforms for product communication
- E-education and use of new media
- Focus on GLOCALISATION\*



# Why is this Important?



## Launch Uptake for Recently Launched Brands in China



Source: IMS CHPA

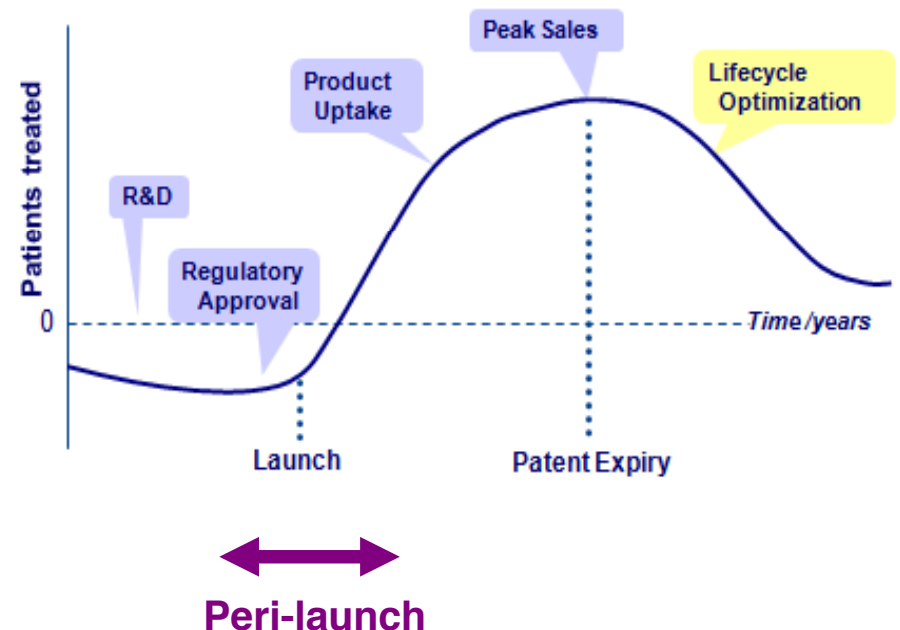
# The Peri-Launch Timeframe: A Key Opportunity for Medical Affairs



## Questions from Doctors

- What are the trial results?
- What do these results mean for my patients?
- Which product should I choose?
- Can I generalize the results to my practice?
- What is the benefit/risk?
- What is the safety profile in “real world”?
- What other studies are needed?
- What other research is being conducted?
  - How can I contribute?

## Typical Product Lifecycle



# MSLs: An Old Idea Driven by Innovation



- Orinase was a first-generation sulfonylurea and the first oral hypoglycaemic drug launched in 1957 by Upjohn (now Pfizer through Pharmacia)
- Widely used in USA and worldwide in the 1960's – considered a major innovation for treatment of diabetes
- The launch of Orinase led to funding by Upjohn for public health efforts to find undiagnosed, asymptomatic diabetics
  - Birth of urine/blood screening and concept of “pre-diabetes”
- **In 1967, Upjohn Company established a “field-based medical support program”**
  - Technically orientated sales representatives
  - Known as **Medical Science Liaisons (MSLs)**
  - To better understand what customers wanted and to leverage Upjohn products into research activities



Research and manufacture of Orinase at the Upjohn plant.

Photo: Al Fenn./Time & Life Pictures/Getty Images May 01, 1957

# Value Proposition for Medical MSL Model



- Defined scope of activities
- Core skills
- Medical Governance
- Relevant Key Performance Indicators (KPIs)
- Networked to R&D/Medical
- Aligned with Business strategies
- Focussed on “peer-to-peer” discussion



**MSL = Content + Communication skills + Alignment + Relevant KPIs + Governance**

# It's a Great Time to be in Medical Affairs!



- **Medical Affairs activity is a key component of a successful product launch and product uptake**
  - New product launches will continue to drive pharma growth and provide benefit to patients
- **Medical Affairs has become even more relevant, but also more complex**
  - We need to evolve and ensure that we have the skills and competencies to be successful both globally and locally
- **The Patient remains our most important customer**
  - Medical Affairs is uniquely placed to focus on patient needs
  - **“Good Medicine is Good Business”**