Do We Need Medical Affairs?

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• 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

Pricing & Reimbursement are becoming more difficult

Continued pressure to manage profitable growth

Growth opportunities in “pharmerging” markets

Continued pressure to manage profitable growth
Novel Ways are Needed to Interact with Physicians

Increasing Difficulty to Reach Physicians

Visit restrictions

<table>
<thead>
<tr>
<th>% of physicians</th>
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<tbody>
<tr>
<td>Restrictions</td>
</tr>
<tr>
<td>70</td>
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Time restriction

<table>
<thead>
<tr>
<th>Min</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
</tr>
<tr>
<td>4.0</td>
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Alternative resources

<table>
<thead>
<tr>
<th>Preferred information source %</th>
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</thead>
<tbody>
<tr>
<td>Independent web sites</td>
</tr>
<tr>
<td>Sales rep</td>
</tr>
<tr>
<td>Medical journals</td>
</tr>
<tr>
<td>Company web sites</td>
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Source: Datamonitor, 2007; EyeforPharma Sales force effectiveness, 2006; BCG analysis
And Organizations Will Need New Skills...

<table>
<thead>
<tr>
<th>Situation in 2000</th>
<th>Situation in 2011</th>
<th>New Skills</th>
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<tbody>
<tr>
<td>• A product with equivalency data will get approved and reimbursed</td>
<td>• Robust Safety, efficacy and value data are essential</td>
<td>• Understand HEOR/Access</td>
</tr>
<tr>
<td>• No major criticism of industry</td>
<td>• Negotiations with government and other stakeholders critical for pricing/reimbursement</td>
<td>• Know how to negotiate with government and other new stakeholders</td>
</tr>
<tr>
<td>• No medicomarketing or compliance codes</td>
<td>• Industry behavior under scrutiny</td>
<td>• Good knowledge of key clinical studies relating to own and competitor products</td>
</tr>
<tr>
<td>• Few if any government audits</td>
<td>• Evolving, stringent and complex codes</td>
<td>• Improve media awareness and ability to present industry issues to media</td>
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<tr>
<td>• Easy access to physicians</td>
<td>• Regular audits</td>
<td>• Participate to influence codes, improve legal understanding</td>
</tr>
<tr>
<td>• Relationship component relevant</td>
<td>• Access to physicians not as easy</td>
<td>• Increase launch and commercial effectiveness</td>
</tr>
<tr>
<td></td>
<td>• Resource constraints</td>
<td>• Knowledge of how to use digital and other new channels</td>
</tr>
<tr>
<td></td>
<td>• New digital channels evolve</td>
<td>• Achieve growth despite cost efficiencies</td>
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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

ISS = Investigator Sponsored Study
KOL = Key Opinion Leader
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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*

EBM = Evidence Based Medicine
MSL = Medical Science Liaison

*Glocalisation is a portmanteau word of globalization and localization. By definition, the term “glocal” refers to the individual, group, division, unit, organisation, and community which is willing and able to “think globally and act locally.”
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

- Time/years
- Patients treated
- Peri-launch

- R&D
- Regulatory Approval
- Launch
- Peak Sales
- Patent Expiry
- Lifecycle Optimization
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”