The Pharma, Biotech and Device Colloquium

Medical Affairs Organization Of The Future

Francois Nader, MD, MBA
Aventis
June 6-9, 2004
Princeton, NJ
Medical Affairs Organization Of The Future

1. The Regulatory Compliance Environment

2. The Medical Affairs Integrated Organizational Model

3. The Medical Affairs Value Propositions
Medical Affairs And The Environment

**ENVIRONMENT**
- OIG
- Hostile Public Opinion
- Medicare Modernization Act

**EXTERNAL**

**DEMAND CUSTOMERS**
- Increasingly under pressure
- Education vs. Selling
- Request Evidence-based Value

**INTERNAL**

**ACCESS CUSTOMERS**
- Critical decision-makers & influencers
- Often underestimated
- Request Evidence-based Value

**R & D**
- Higher R&D Cost
- Fewer NCE’s
- Current brands have to last longer and generate more
Medical Affairs Organizational Model: “One-Stop-Shop”

INTEGRATED SCIENTIFIC SUPPORT THROUGHOUT THE LIFECYCLE

HEALTH OUTCOMES

MEDICAL RESEARCH

MEDICAL EDUCATION

REGULATORY SUPPORT

MEDICAL BUSINESS OPERATIONS

MEDICAL COMMUNICATIONS

- Therapeutic & Brand MD’s
- Clinical Supplies
- Study Management
- Biometrics
- Medical Liaison

- Program Management
- Outsourcing
- IS
- HR
- Finance
- Resource Management

- Medical Information
- Scientific Publications
- E-Medical

- Copy Review
- Compliance
- Labeling
- Drug Safety

Francois Nader – Aventis
Medical Affairs Value Propositions: a Catalyst and a Player in Maximizing The Brand Potential

- Medical Research
- Medical Education
- Medical Communications
- Outcomes Solutions
- Regulatory Support

Sales

Rapid Uptake

Higher Peak Sales

Longer Time on the Market

Launch 2 3 4 5 - - - - - - N

Years

Francois Nader – Aventis
Medical Affairs Value Propositions: Uniquely Positioned Bridge Between R&D and Commercial

R & D
I  II a  II b  III  Filing  Approval

Medical Affairs

Medical Research

Medical Education

Health Outcomes Research

Medical Communications

Regulatory Support

Shape the Market

Brand Lifecycle

Phase III b
- New Indications
- Special Population

- Opinion Leaders Development
- Investigators Selection
- Educational Programs
- Evidence Based Medicine Paradigm Shift

- Health Ec Dossier (AMCP)
- Health Outcomes Solutions

- Publications
- Medical Information

- Copy Review
- Regulatory Compliance
Medical Affairs Value Propositions:
Characterize, Generate and Communicate Evidence - Based Value to the Key Stakeholders

- Accreditation Bodies
- Academics
- Thought Leaders
- Providers
- Payers
- Government
- Employers

MEDICAL AFFAIRS
In Summary, A Successful Medical Affairs Organization

- Positions itself as the primary source of scientific support throughout the lifecycle
- Plays within the evolving rules of regulatory compliance and take advantage of the external & internal drivers
- Is built on a sound organizational model that is compliant and integrated in a “one-stop-shop” approach
- Develops unique Value Propositions
  - As a catalyst and a player in maximizing a brand potential
  - As a unique bridge between R&D and Commercial
  - As a leader in characterizing, generating and communicating evidence-based value to key stakeholders