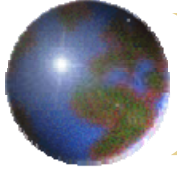


# *Medical Information in Europe*

Janet Davies

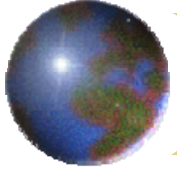
Medical Information Director, Europe,  
Middle East and Africa  
Bristol-Myers Squibb

DIA Medical Communications SIAC,  
European Co-Chair



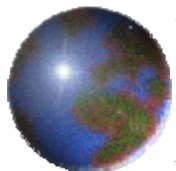
## *Outline*

- Terminology
- Business Rationale
- Regulatory and Legal Aspects
- Role and Activities of Medical Information
- Regulatory Inspections
- Drug Information Association



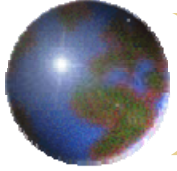
## *Medical Information In Europe*

- MI activities in all countries
  - Growing demand for MI
  - Variations in extent of service and activities
  - Cultural differences in customer expectations
  - Increasing regulatory focus
- 
- About 1500 people in role in EU across pharmaceutical industry



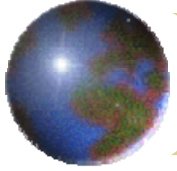
## *What's In A Name?*

- Medical Information
- Drug Information
- Medical Communications
- Medical Services
- Professional Services
- Scientific Information
- Documentalist



## *What is Medical Information?*

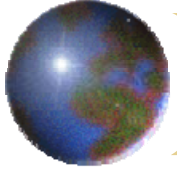
Knowledge and information service for healthcare professionals and patients who have scientific or medical questions about a company's medicinal products.



## *Business Rationale*

- Customer expectations
- Market demand
- Legal requirement
- Ethical requirement
- Emphasis on evidence-based medicine

Medical Information is a critical business  
function



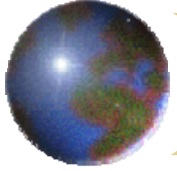
## *EU Directive*

### ● European Union Council Directives

2004/27/EC and 2001/83/EC (previously 92/28/EEC)

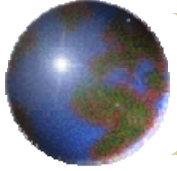
<http://dg3.eudra.org/F2/review/index.htm>

“The marketing authorization holder shall establish within his undertaking a scientific service in charge of information about the medicinal products which he places on the market.”



## *EFPIA Code*

- EFPIA Code of Practice on the Promotion of Medicines, November 2004  
[http://www.efpia.org/6\\_publ/default.htm](http://www.efpia.org/6_publ/default.htm)
- Correspondence to answer a specific question about a medicinal product is not a promotional activity
- Must respond promptly to reasonable requests from healthcare professionals

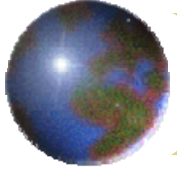


## *Country Codes*

- ✦ May include more detailed guidance
- ✦ Responses to individual enquiries are regarded as non-promotional if:
  - ❑ Request is unsolicited
  - ❑ Relates solely to subject of request
  - ❑ Accurate and not misleading
  - ❑ Not promotional in nature

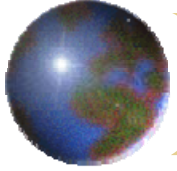
UK Code of Practice for the Pharmaceutical Industry 2006

<http://www.abpi.org.uk/links/assoc/PMCPA/code06use.pdf>



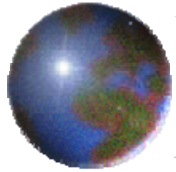
## *Customer Contacts*

- Prescribers
- Other healthcare professionals
- Key Opinion Leaders
- Formulary decision makers
- Purchasers
- Patients



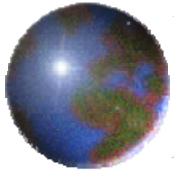
## *Role of Medical Information*

- Share knowledge and information about the company's medicinal products
- Provide the information and evidence that healthcare professionals need



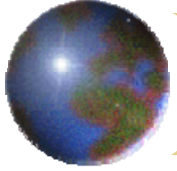
## *Contact with Healthcare Professionals*

- Explain SPC content
- Provide product information beyond the SPC – “off-label”
- Provide information for patient-treatment decisions
- Provide service for medical emergencies
- Identify potential adverse events



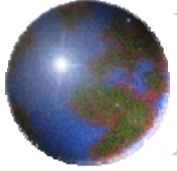
## *Medical Information Activities*

- Responding to customer requests
  - Searching published and unpublished information sources
  - Writing standard and customised responses
- Proactive management of product issues
  - Supply, discontinuation, Dear HCP letters
- Information and knowledge management
  - Maintaining standard responses
  - Maintaining published literature collections
- Promotional material review



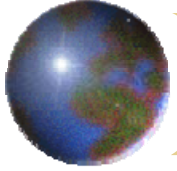
## *Contact with Patients*

- Medical Information is a contact point for patients and carers
- Patient Information Leaflets include company contact information
- No advice on personal medical matters
  - EFPIA Code, Article 8
- Country specific guidelines on the extent of contact



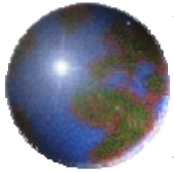
# *Regulatory Inspections*

- Pharmacovigilance inspections by EU Regulatory Authorities will focus on Medical Information
  - Procedures
  - Enquiry databases
  - Out of hours cover
  - Information resources

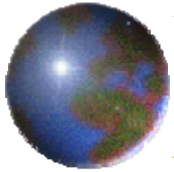


## *Medical Information in Europe*

- Exists in all countries
- Variations in extent of service and activities
- Cultural differences in customer expectations
- Growing demand
- Regional approach to MI is increasing

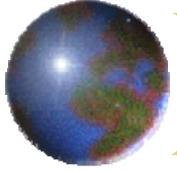


**DRUG INFORMATION ASSOCIATION**



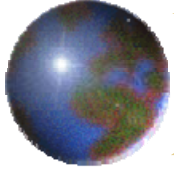
# *Drug Information Association*

- Professional association of 23,000 members worldwide
  
- Nonprofit, multidisciplinary, neutral forum for sharing information that optimizes the process of drug development and lifecycle management by providing:
  - Global and regional forums for the exchange of information, education, and training
  - Extensive multidisciplinary networking opportunities
  - Rewarding volunteer leadership experiences
  - High-quality professional development opportunities



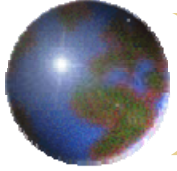
# *Medical Communications SIAC* *(Special Interest Area Committee)*

- Active SIAC - especially in US
- Medical Communications typically includes:
  - Medical Information
  - Field Medical
  - Customer Contact Centres
  - Promotional Affairs
- Annual workshop in US in March
  - 350 delegates + Exhibition
  - Programme is US focused



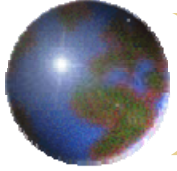
## *Mission of Medical Communications SIAC*

- To provide a professional, neutral forum for discussion of issues and best practices related to medical communications components within the pharmaceutical and biotech industries, with an emphasis on the creation and provision of high-quality medical information to address the inquiries of healthcare professionals.
- To both determine and address the educational needs of DIA members whose interest area is medical communications through such activities as:
  - Designing and conducting introductory-, intermediate-, and advanced-level courses and workshops under DIA auspices.
  - Contributing to DIA's Annual Meeting and EuroMeeting.
- To raise awareness of medical communications and to encourage dialogue among regulators, academic institutions, and other industry personnel.



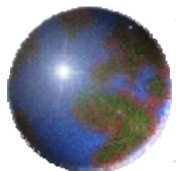
## *Goals of DIA Medical Communications SIAC in Europe*

- Create a European community of professionals working in medical communications within the pharmaceutical industry
- Create a focal point for fellow Medical Communications SIAC members working in other regions (North America, Japan, Asia)



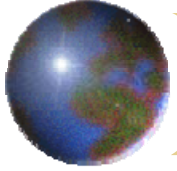
## *Why focus on Europe?*

- Unmet need
  - Community size – 1500 people across Europe
  - Limited national associations for Medical Information
    - France, Italy, UK
    - None aim to span Europe
- Little competition - very few European meetings in same field
- High interest from Medical Information community
- Fits well with DIA EuroMeeting programme – patient information, pharmacovigilance & promotional regulatory aspects



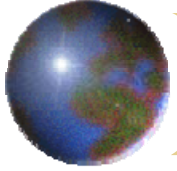
## *DIA EuroMeeting 2006*

- Single day devoted to Medical Information
  - Medical Information in Europe
  - European Collaboration – company views
  - Regulations, Codes of Practice, QA
  - Patient Communications
- 75 attendees with Medical Information experience



## *Future Plans*

- Proposal submitted for Medical Information Track at DIA EuroMeeting in 2007
- Outline programme for stand-alone workshop
- Develop a European Medical Information Community



## *Medical Information in Europe*

- Exists in all countries
- Variations in service and activities
- Regulatory focus increasing
- Companies taking a Regional approach
- Strong need for a European forum for MI professionals