SIFEIT
Società Italiana per Studi di Economia ed Etica sul Farmaco e sugli Interventi Terapeutici

SOCIETÀ DI SCIENZE FARMACOLOGICHE APPLICATE
SOCIETY FOR APPLIED PHARMACOLOGICAL SCIENCES
FONDATA NEL 1964

SEMINARIO DI AGGIORNAMENTO
GOVERNANCE DEI PROCESSI AZIENDALI
IL RUOLO DEL MEDICAL AFFAIRS

26 Gennaio 2017

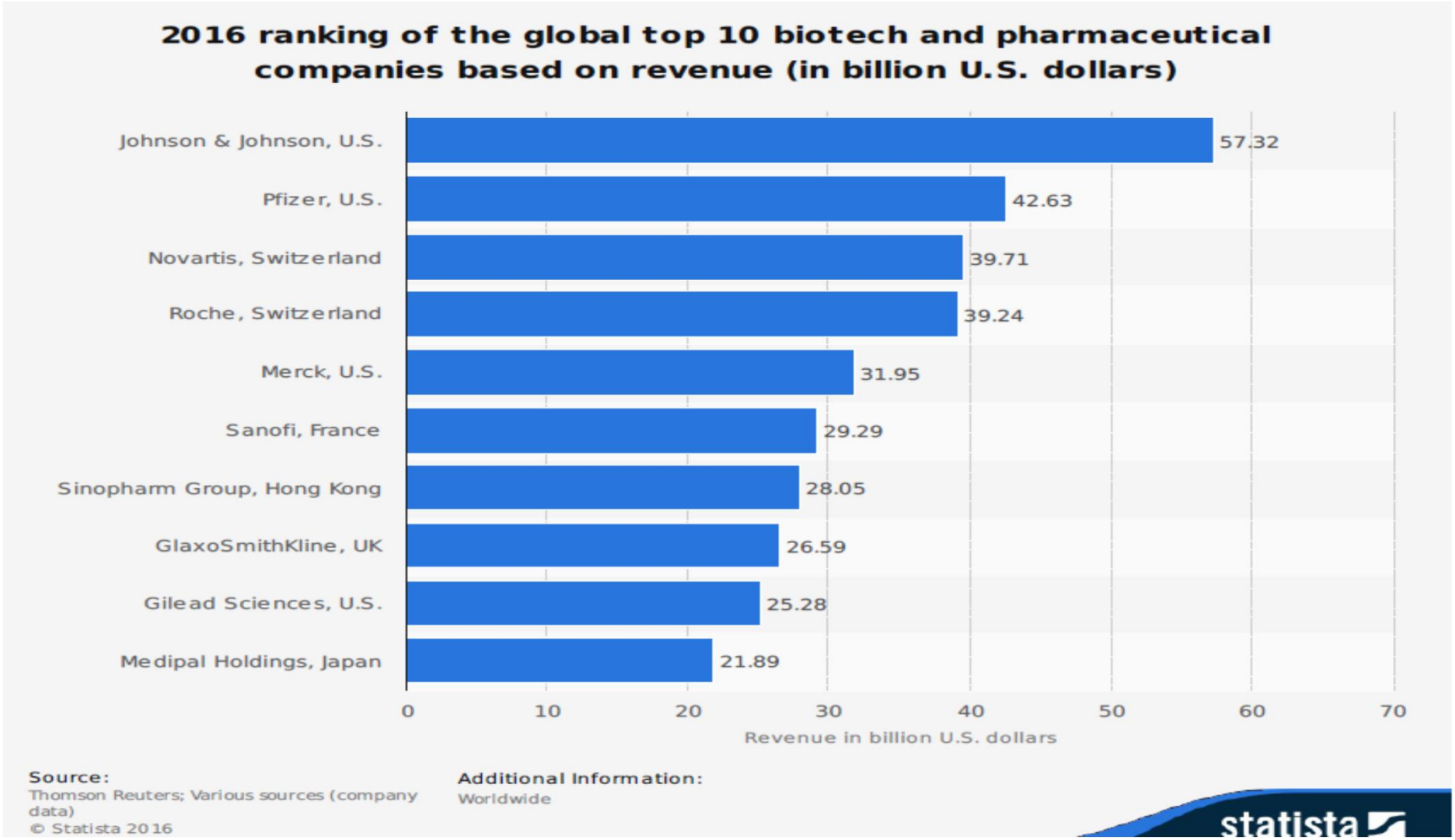
Aula Celli
Dipartimento di Sanità Pubblica e Malattie Infettive
Sapienza Università di Roma
Piazzale Aldo Moro 5, 00185 Roma

Dipartimento di Sanità Pubblica e Malattie Infettive
SAPIENZA Università di Roma

I modelli di governance dei processi nelle multinazionali

Federico Pantellini, MD
Medical Affairs Director Hematology-Oncology
Celgene srl
Roma 26/01/2017

Summary


2016 ranking of the global top 10 biotech and pharmaceutical companies based on revenue (in billion U.S. dollars)
Johnson & Johnson, U.S.
57.32
Pfizer, U.S.
42.63
Novartis, Switzerland
39.71
Roche, Switzerland
39.24
Merck, U.S.
31.95
Sanofi, France
29.29
Sinopharm Group, Hong Kong
28.05
GlaxoSmithKline, UK
26.59
Gilead Sciences, U.S.
25.28
Medipal Holdings, Japan
21.89
0
10
20
30
40
50
60
70
Revenue in billion U.S. dollars
Source:
Thomson Reuters; Various sources (company data)
© Statista 2016
Additional Information:
Worldwide
statista

The transatlantic industry today*

8 OUT OF THE TOP **10**
PHARMA COMPANIES ARE FROM EUROPE OR THE US

80%
OF GLOBAL SALES OF PHARMA

60%
OF US PHARMA IMPORTS ARE FROM THE EU

75% OF GLOBAL R&D IN LIFE-SCIENCE TAKES PLACE IN THE EU & US

efpia
European Federation of Pharmaceutical Industries and Associations

The Pharmaceutical Industry in Figures

Key Data * 2016

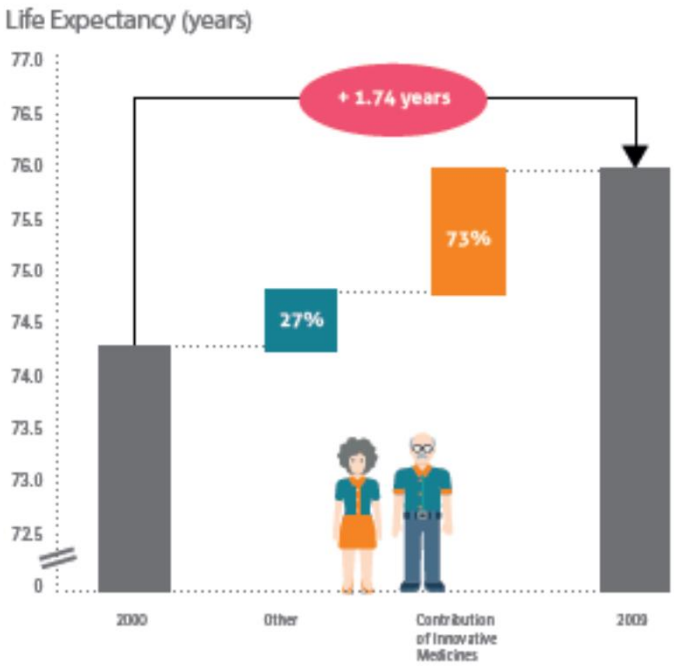
INDUSTRY (EFPIA total)	2000	2010	2014	2015
Production	125,316	199,400	221,088	225,000 (e)
Exports (1) (2)	90,935	276,357	324,452	361,500 (e)
Imports	68,841	204,824	251,427	275,000 (e)
Trade balance	22,094	71,533	73,025	86,500 (e)
R&D expenditure	17,849	27,920	30,887	31,500 (e)
Employment (units)	534,882	670,088	723,448	725,000 (e)
R&D employment (units)	88,397	117,035	118,052	118,000 (e)
Total pharmaceutical market value at ex-factory prices	86,446	153,118	183,924	192,000 (e)
Payment for pharmaceuticals by statutory health insurance systems (ambulatory care only)	76,909	129,464	124,273	126,000 (e)

efpia
European Federation of Pharmaceutical Industries and Associations

The Pharmaceutical Industry in Figures

Key Data ✱ 2016

CONTRIBUTION OF INNOVATIVE MEDICINES TO INCREASE IN LIFE EXPECTANCY (2000–2009)



✱ From 2000–2009, an improvement in population weighted mean life expectancy at birth of 1.74 years was seen across 30 OECD countries.

✱ Innovative medicines are estimated to have contributed to 73% of this improvement once other factors are taken into account (e.g. income, education, immunization, reduction in risk factors, health system access).

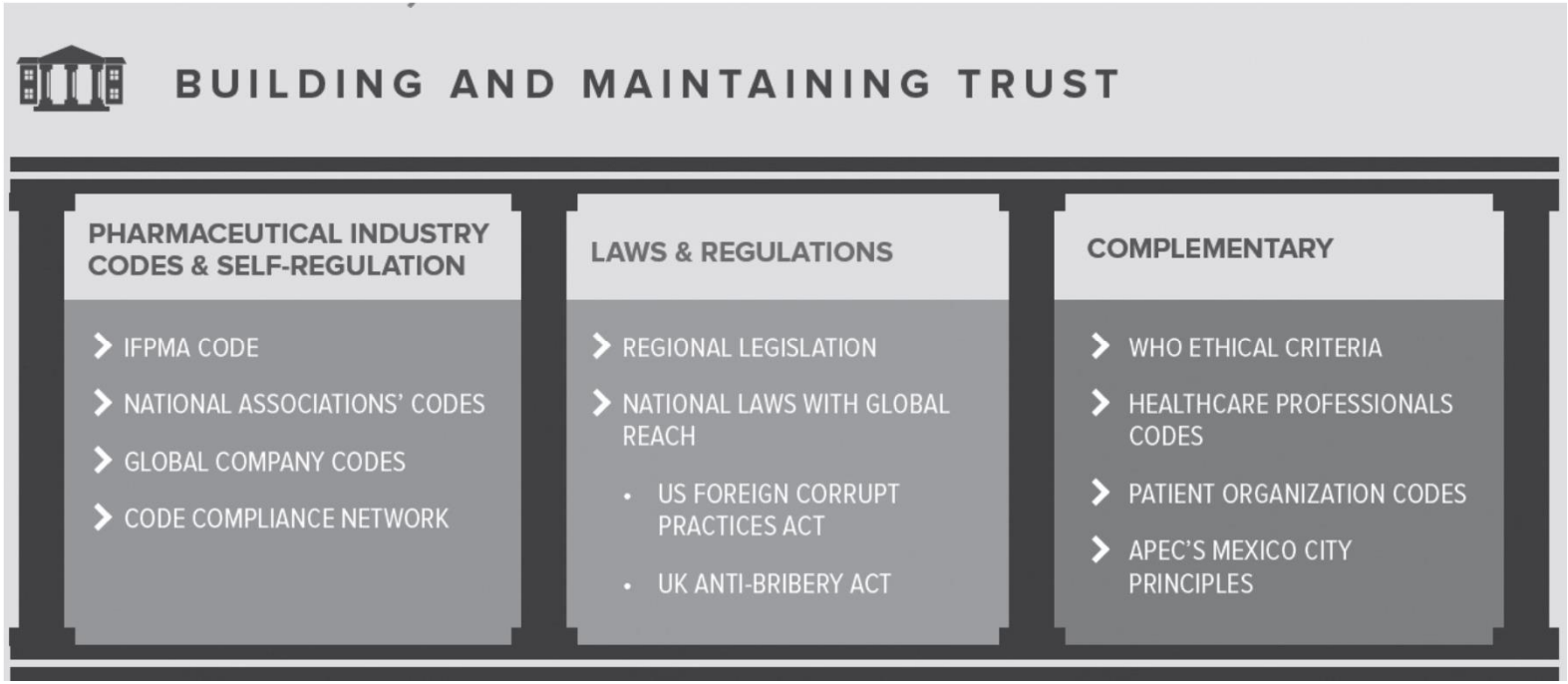
Source: Lichtenberg, F: Pharmaceutical innovation and longevity growth in 30 developing OECD and high–income countries, 2000 – 2009 (2012)

Medical Affairs teams today play a key role in the information flow between the Commercial and R&D operations.

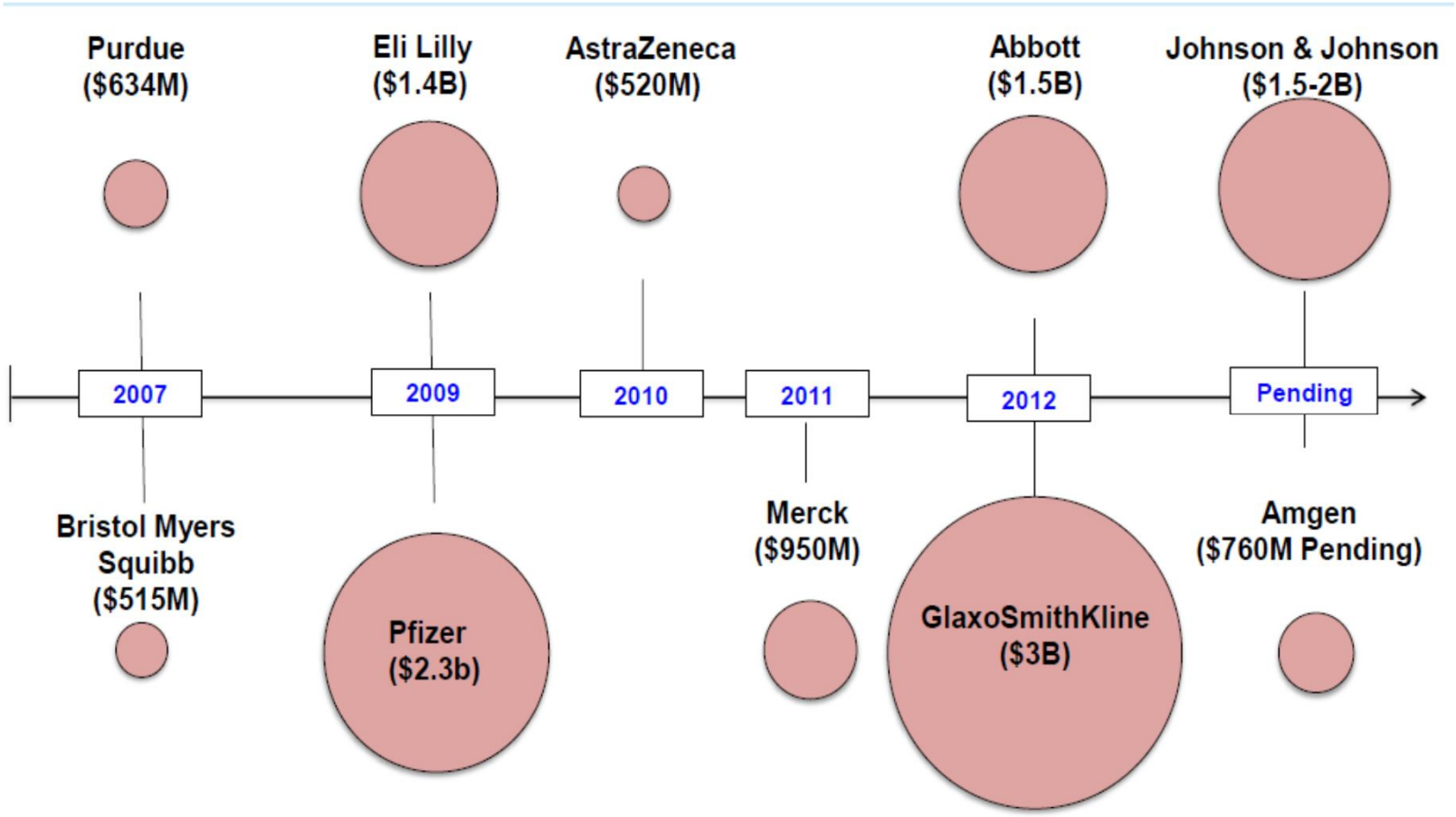
Commercial

- The changing healthcare environment has encouraged the formation of independent Medical Affairs departments.
- However, there is not a rigid set of requirements that dictate how a Medical Affairs department should look or operate.
- As a result, the industry has developed a wide variety of models, all seeking to address intensified public and regulatory scrutiny.

R&D


BUILDING AND MAINTAINING TRUST
PHARMACEUTICAL INDUSTRY CODES & SELF-REGULATION
IFPMA CODE
NATIONAL ASSOCIATIONS' CODES
GLOBAL COMPANY CODES
CODE COMPLIANCE NETWORK
LAWS & REGULATIONS
REGIONAL LEGISLATION
NATIONAL LAWS WITH GLOBAL REACH
US FOREIGN CORRUPT PRACTICES ACT
UK ANTI-BRIBERY ACT
COMPLEMENTARY
WHO ETHICAL CRITERIA
HEALTHCARE PROFESSIONALS CODES
PATIENT ORGANIZATION CODES
APEC'S MEXICO CITY PRINCIPLES

Big Pharma settlements since 2007



M & SA : The New Industry Model

Paradigm shift in how Science has been communicated to the doctors till date.

Conventional Vs Unconventional (emerging)

- Promotion Vs Education
- Drugs Vs Disease
- Push Vs Pull
- Business development (predominantly the sales push model) Vs Developing the business (predominantly the scientific pull model)
- Value addition Vs Value creation
- Carpet bombing communication Vs Individualized Communication

efpia

European Federation of Pharmaceutical Industries and Associations

Understanding the working relationship between the pharmaceutical industry and healthcare professionals

Sharing knowledge – improving patient care

The pharmaceutical industry regularly works in close collaboration with healthcare professionals (HCPs) towards a shared objective of improving the lives of patients through medical advances and enhanced care. This longstanding and well-regulated relationship plays a vital role in the research and development of life-saving medicines and their use in clinical practice.

At the core of the relationship is sharing knowledge to improve patient outcomes. The medical profession offers the industry invaluable insights into areas of unmet medical need, potential therapeutic solutions and the everyday application of treatments in the clinic. In turn, the industry provides HCPs with the chance to shape the therapeutic landscape through clinical research programmes and with peer-to-peer learning opportunities.


About the EFPIA Disclosure Code

Securing the future of collaboration between industry and healthcare professionals

Industry and HCPs collaborate on a range of activities from clinical research, sharing best clinical practice and exchanging information on how new medicines fit into the patient pathway. EFPIA believes HCPs should be fairly compensated for the legitimate expertise and services they provide to the industry.

Bringing greater transparency to this, already well-regulated and vital relationship builds understanding of industry-HCP/HCO collaboration and, in the context of increasing societal expectations on transparency, addresses directly public concerns about interactions between the medical community and the pharmaceutical industry.

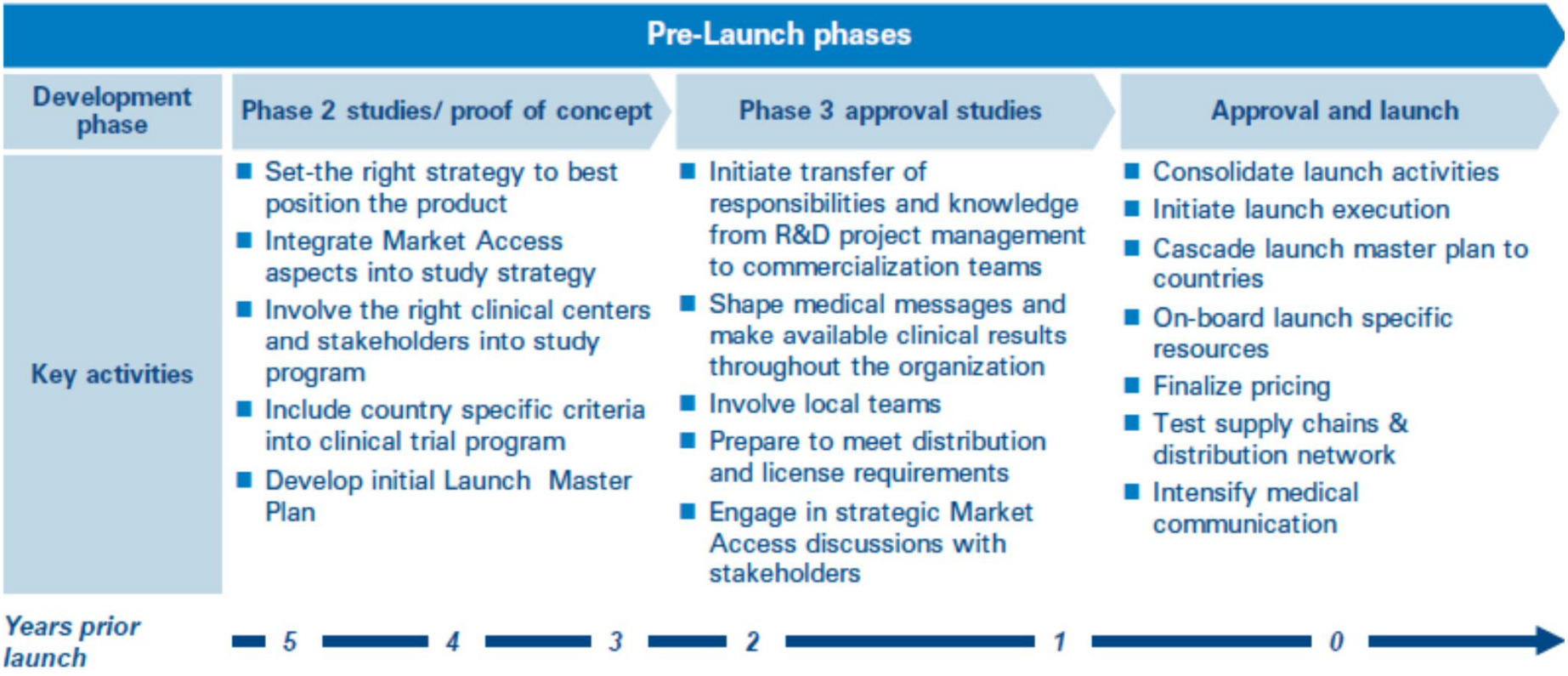
That is why, by 30 June 2016, companies will begin disclosing transfers of value made to HCPs, such as consultancy and advisory boards, speaker fees, and sponsorship to attend meetings. This transformational step in the relationship between industry and health professionals is a result of the EFPIA Disclosure Code.

Medical Governance in pharma industry (1)

- *Appropriate Medical Governance at pharma companies is increasing in need, scope, and importance in the industry.*

- *The patient should be at center of every decision making process*

- *The public, regulators, providers, and markets expect that principles of good medical science and ethical standards are consistently applied globally across the product lifecycle from development to post-marketing surveillance and promotional practices all the way through to product withdrawal.*


Pre-Launch phases
Development phase
Phase 2 studies/ proof of concept
Phase 3 approval studies
Approval and launch
Key activities
Set-the right strategy to best position the product
Integrate Market Access aspects into study strategy
Involve the right clinical centers and stakeholders into study program
Include country specific criteria into clinical trial program
Develop initial Launch Master Plan
Initiate transfer of responsibilities and knowledge from R&D project management to commercialization teams
Shape medical messages and make available clinical results throughout the organization
Involve local teams
Prepare to meet distribution and license requirements
Engage in strategic Market Access discussions with stakeholders
Consolidate launch activities
Initiate launch execution
Cascade launch master plan to countries
On-board launch specific resources
Finalize pricing
Test supply chains & distribution network
Intensify medical communication
Years prior launch
5
4
3
2
1
0

Medical Governance in pharma industry (2)

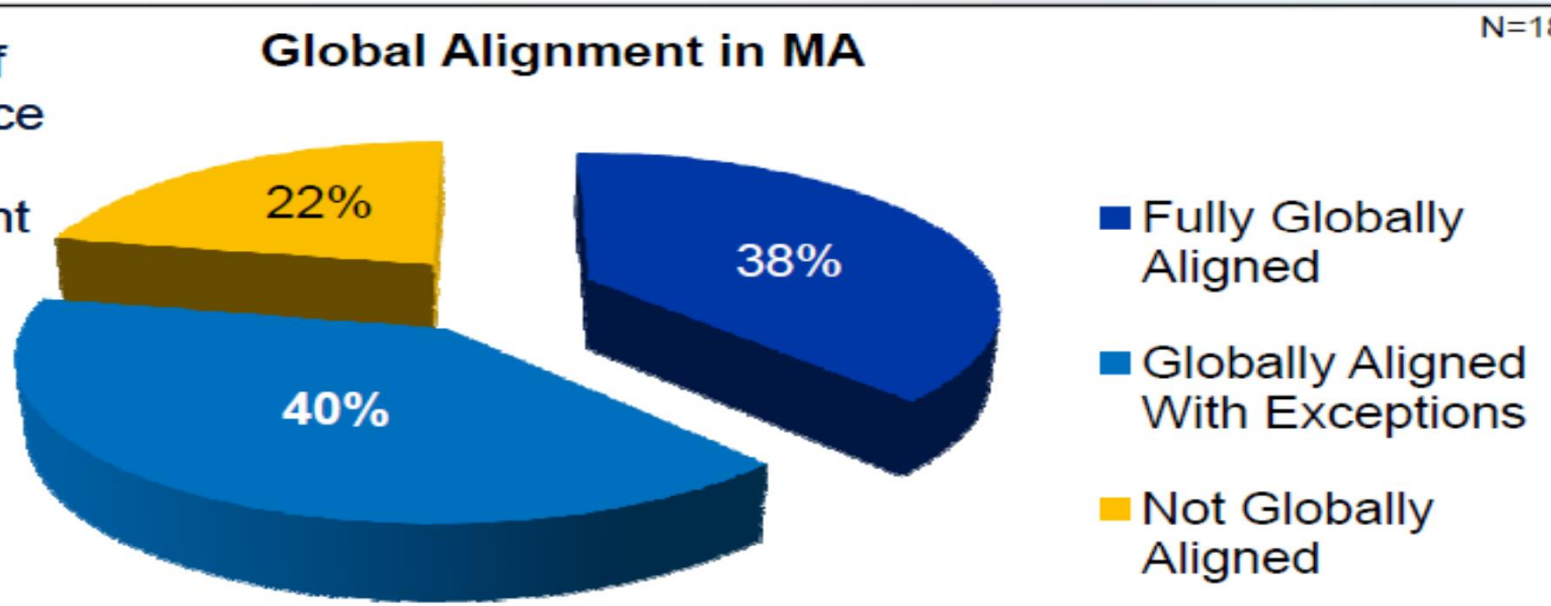
- In order to successfully operate in this environment, companies must be able to navigate through evolving regulatory requirements and have in place:

Pharma Organizations models

Global Coordination in Medical Affairs:

Need for Global Coordination—Different Compliance Regimes

Given the range of different compliance regimes, our data shows that different organizations are taking very different approaches.

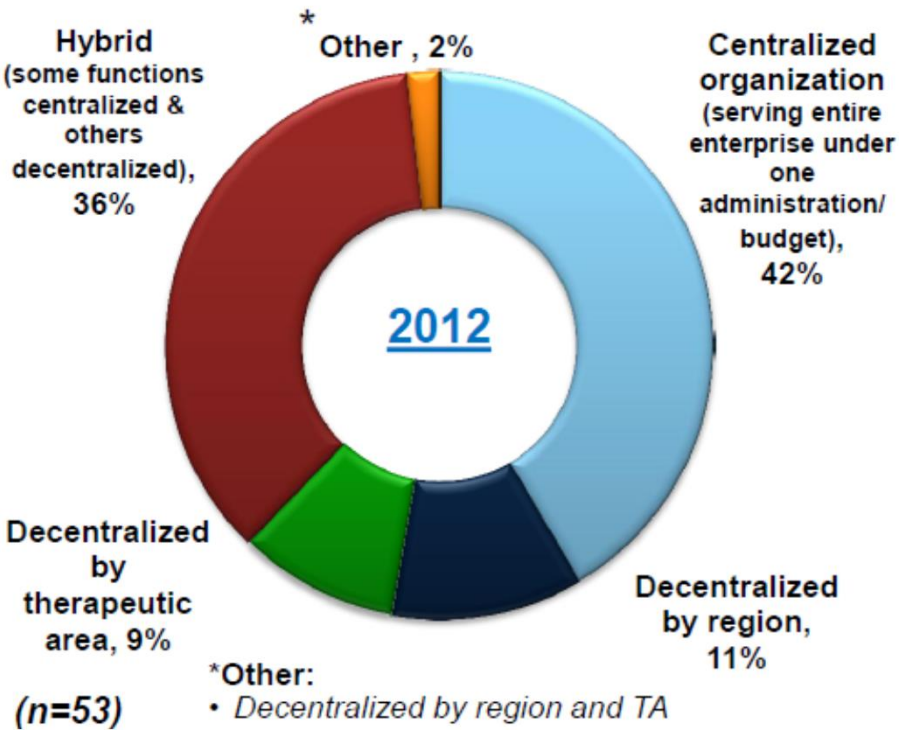


Source: Campbell Alliance Medical Affairs Leadership Summit Benchmarking Survey of 18 Medical Affairs Leaders, July 2011.

Most surveyed global MA organizations have at least partial alignment.

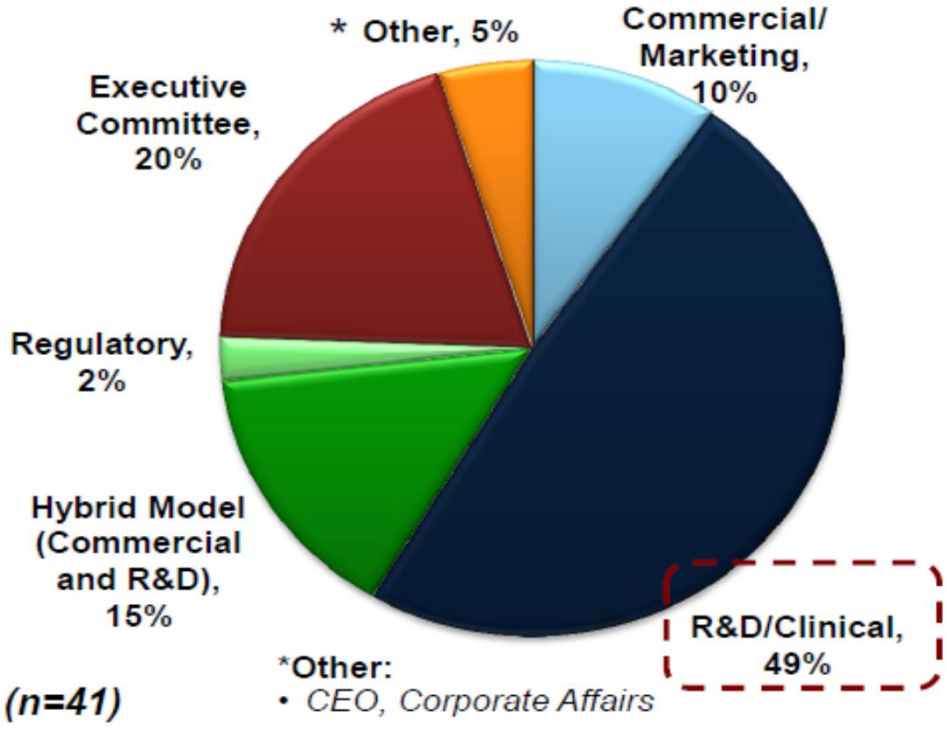
Medical Affairs Organizations
Centralized, decentralized or hybrid models?

Mature Markets Segment:

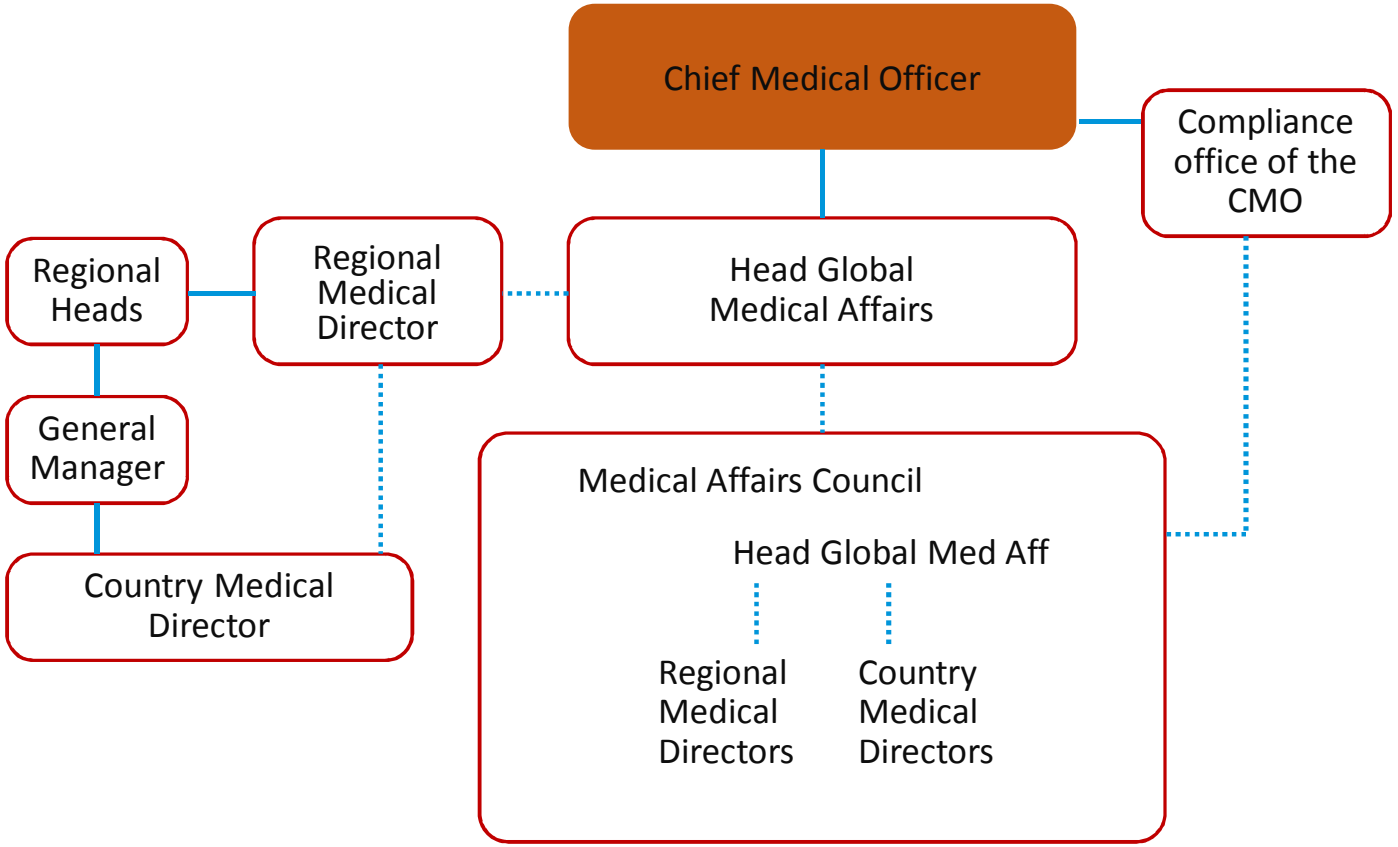


Reporting Relationship

Pharma Segment:



A Decentralized Model example

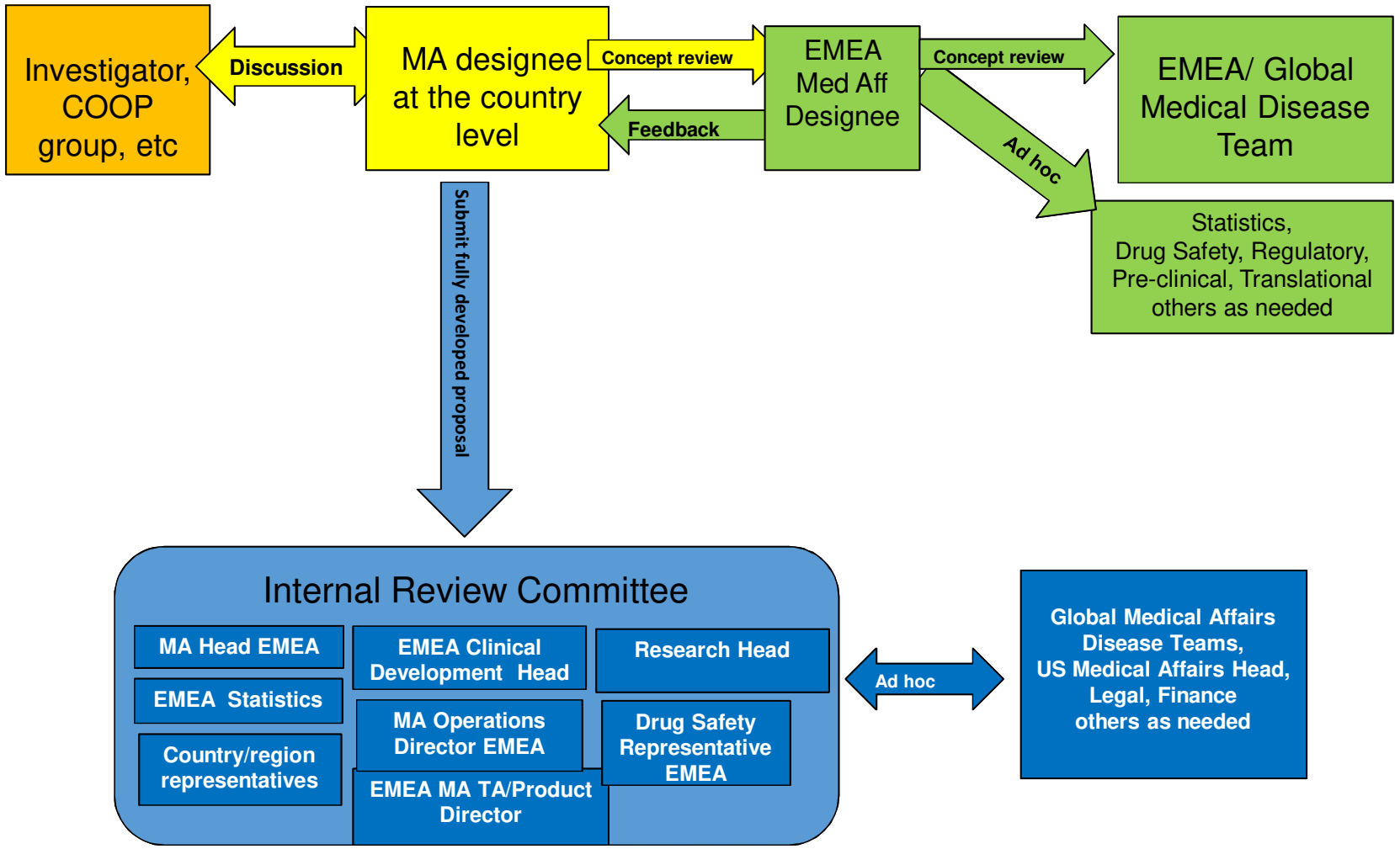


Medical Governance in pharma industry (3)

Global Coordination in Medical Affairs:

Functions Requiring Global Coordination—Overview

Independent study proposals
Governance Process overview



Education vs promotion

Education vs promotion

Our Code of Practice
for promotion and scientific engagement (prescription medicines)

Scientific engagement (non-promotional)

Scientific engagement is the non-promotional interaction and exchange of information between GSK and external communities in order to advance scientific and medical understanding. This includes the appropriate development and use of our medicines, understanding the management of disease, and improving patient care.

The activities and materials associated with scientific engagement are non-promotional in nature and intent, and proportional to the scientific need. There is a clear distinction between scientific engagement and promotional activities.

Accountability and approval for scientific engagement activities resides within our Medical Governance Framework to ensure that the content, frequency, and other aspects of scientific engagement are appropriate and proportionate to genuine scientific and public health need.

Budgets for scientific engagement activities are under R&D/Medical accountability.

The relevant Medicine or Vaccine Development Leader (MDL/VDL) is accountable for scientific engagement and approval of scientific engagement activities from Commit to Medicine Development to marketing authorisation.

- Prior to the assignment of the MDL/VDL for a medicine, the most appropriate member of the R&D leadership team from within the relevant research unit is accountable for ensuring that the principles of scientific engagement are appropriately applied.

Once a medicine (or new indication) receives marketing authorisation in at least one key market (eg USA, EU or a franchise market), approval for post-authorisation activities is in line with the level in the organisation where the activity is organised, eg relevant Global Medical Affairs Leader (GMAL or assigned individual where there is not a GMAL) for a global activity, Area Medical Lead for an area activity, Country Medical Director (CMD) for a LOC activity (in countries where a CMD role does not exist, the Area Medical Director is accountable).

Medical affairs role in promotional activities

1.4.1 All promotional meetings

The purpose of our promotional meetings is to proactively provide scientific or medical information about our authorised medicines and/or the associated diseases.

- Meetings (including third party medical education events) that we influence (eg by suggesting or providing content or by selecting/recommending speakers) are GSK promotional meetings. They are promotional meetings whether or not they are awarded continuing medical education (CME) points or other continuous professional development credits.

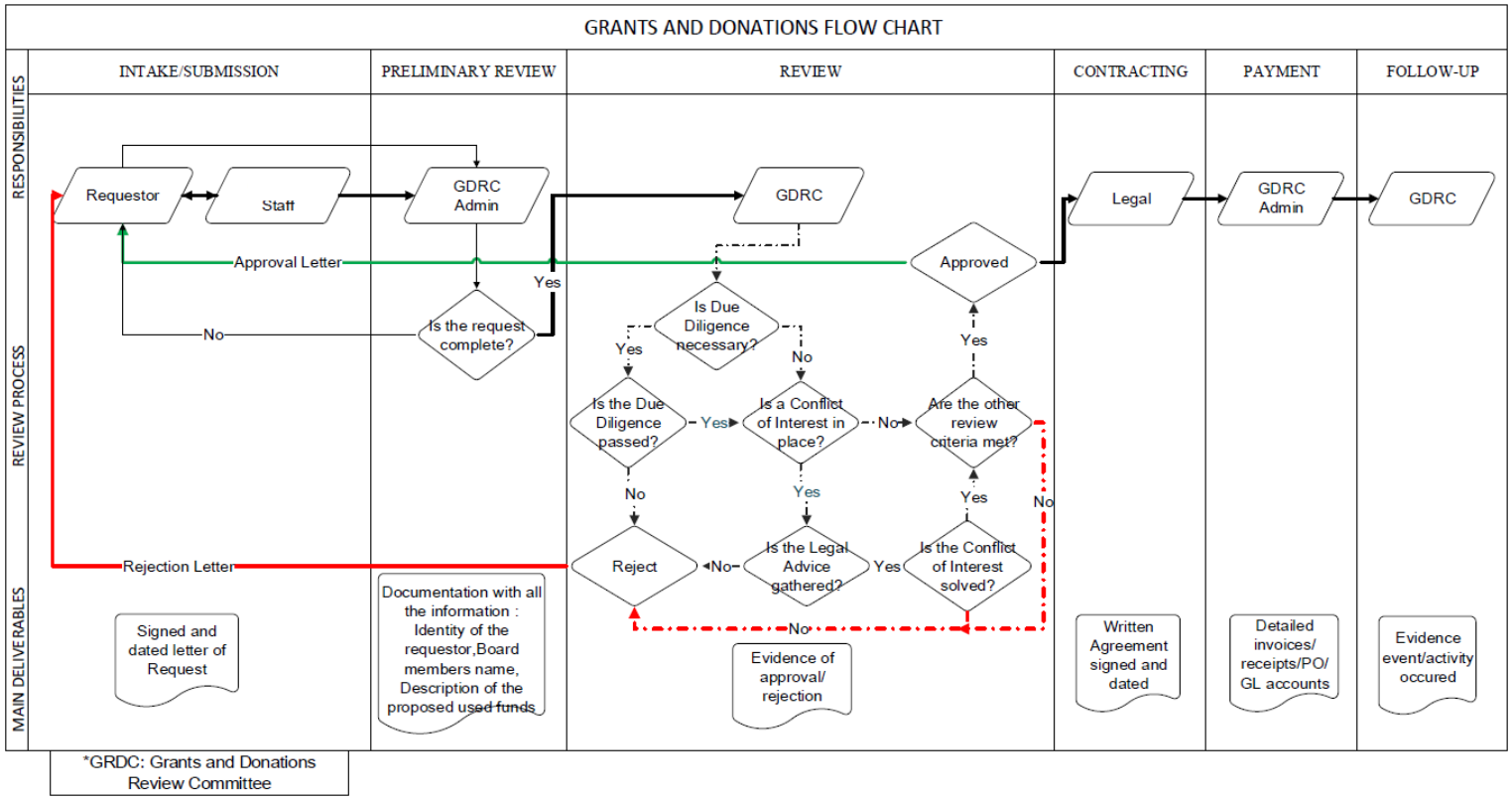
Promotional meetings only occur when we are able to ensure that the meeting adheres to the requirements of this section and other relevant requirements of this code including that the data presented and materials provided do not promote off-label use of our medicines.

1.4.6 GSK sponsored satellite symposia

Satellite symposia may be under Commercial or Medical budget. Medical has accountability for the content of GSK sponsored satellite symposia.

- The scientific and medical content of a satellite symposium and the appropriateness of the speaker faculty are approved by the relevant CMD or designee for the country in which the event occurs (see above for additional approvals for HCPs/OHS who agree to speak without a payment). Logistical arrangements may be implemented by non-medical teams or a contracted vendor.

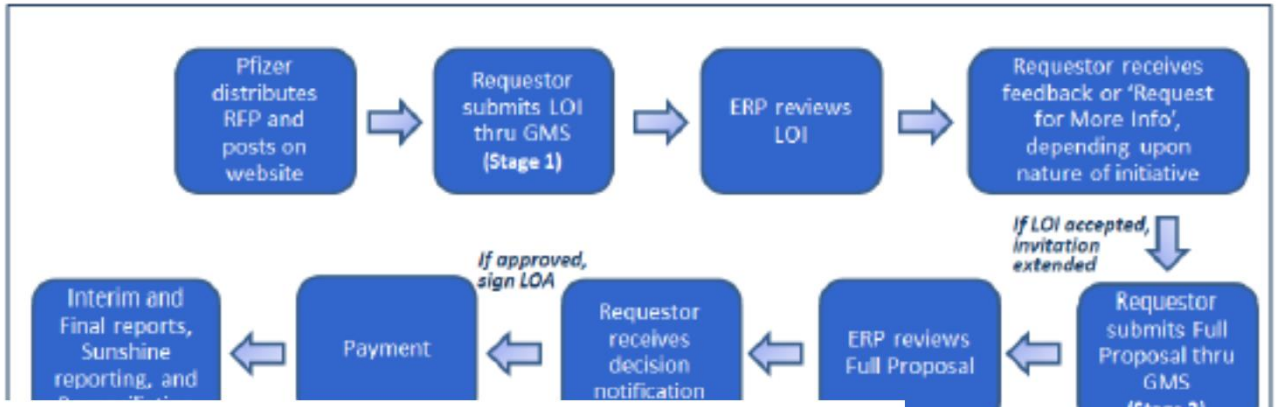
Grants & Donations



Independent Grants for Learning & Change (IGLC)

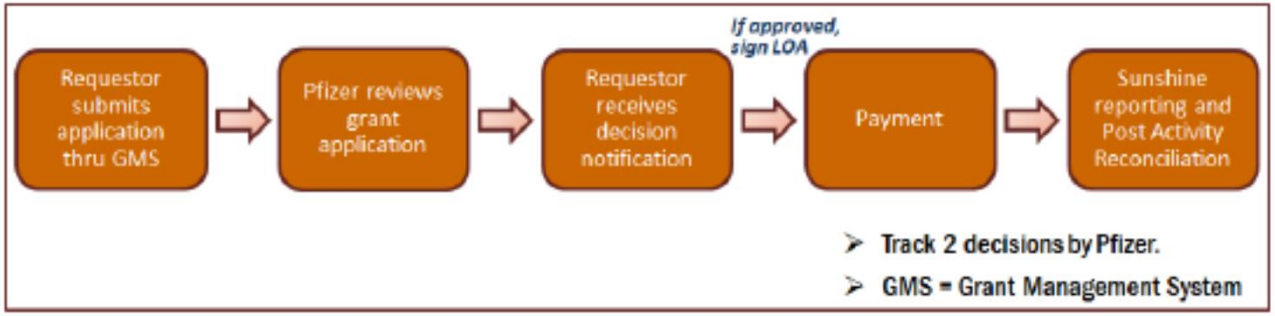
~ Process Overview ~

Track 1 – Learning & Change



a two-stage application process;
by External Review Panel.
ınt Management System

Track 2 – Knowledge Gap



- Track 2 decisions by Pfizer.
- GMS = Grant Management System

Some considerations

Restoring the pharmaceutical industry's reputation

Mark Kessel

Big pharma's storehouse of trouble has fostered consumer mistrust and a negative view of the industry. How does the industry go about restoring its flagging reputation?

To restore its good name, the pharmaceutical industry has to radically alter the way it is perceived by the public. The good news is that as the damage was self-inflicted, it should be possible to address it.


STVDIVM VRBIS
CTRINA - EADEM - VIDETVR - ET - RECTE - FACIENDI - ET - BENE