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Dr. Shereef Ibrahim



Medical Affairs Club

**The Power Behind the Message:
Standards for medical review of
promotional materials**

Online zoom

7 pm Egy - 8 pm KSA - 9 pm UAE



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The Power Behind the Message:

Standards for medical review of promotional materials

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Medical Advisor,
Organon





Disclaimer



- All information, opinions, examples presented in this session are based solely on my own experience and doesn't represent my current or former employers.

About me



2003-2008



2008



2008-2009



2009-2021



2021-Date



2019



Imagine waking up to this news!

\$ 500M



The screenshot shows the top of a Financial Times article. At the top is the 'FINANCIAL TIMES' logo. Below it is a navigation bar with links: HOME, WORLD, US, COMPANIES, TECH, MARKETS, CLIMATE, OPINION, LEX, WORK & CAREERS, LIFE & ARTS, HTSI. The article title is 'Teva Pharmaceutical Industries Ltd' followed by a button '+ Add to myFT'. The main headline is 'EU fines world's largest generic drugmaker [REDACTED] for hindering competition'. Below the headline is a sub-headline: 'European Commission says company abused 'dominant position' to 'artificially' extend patent protection of MS medicine [REDACTED]'.

FINANCIAL TIMES

HOME WORLD US COMPANIES TECH MARKETS CLIMATE OPINION LEX WORK & CAREERS LIFE & ARTS HTSI

Teva Pharmaceutical Industries Ltd + Add to myFT

EU fines world's largest generic drugmaker [REDACTED] for hindering competition

European Commission says company abused 'dominant position' to 'artificially' extend patent protection of MS medicine [REDACTED]

It also said that [REDACTED] misused patent procedures and targeted doctors and authorities in charge of pricing and reimbursement of medicines with misinformation about the “safety, efficacy and therapeutic equivalence” of a rival drug in order to delay competition and prolong the exclusivity of [REDACTED]

<https://www.ft.com/content/17da3c62-d901-49b3-bf40-14742177a31f>

Imagine waking up to this news!

Press Release 27 March 2024

██████ and ██████ named in advertisements for breaches of the ABPI Code

██████ and ██████ have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Clause 2 – Bringing discredit upon, and reducing confidence in, the pharmaceutical industry

Clause 3.2 – Promoting a medicine in a manner that was inconsistent with the particulars listed in its summary of product characteristics

Clause 4.1 – Failing to include prescribing information

Clause 4.9 – Failing to include the prominent adverse event reporting statement

Clause 4.10 – Failing to include a black triangle

Clause 7.11 – Referring to a product as 'new' when it has generally been available for more than 12 months in the UK

Clause 9.1 – Failing to maintain high standards

<https://www.pmcpa.org.uk/about-us/media/news/teva-and-daiichi-sankyo-named-in-advertisements-for-breaches-of-the-abpi-code>



**"In God we trust.
All others must bring data."**

- Dr. W. Edwards Deming



صلاح جاهين

الكلمة إيد، الكلمة رجل، الكلمة باب،
الكلمة نجمة كهربية في الضباب
الكلمة كوبري صلب فوق بحر
العباب،
الجن يا أحباب، ما يقدر يهدمه..
فاتكلموا

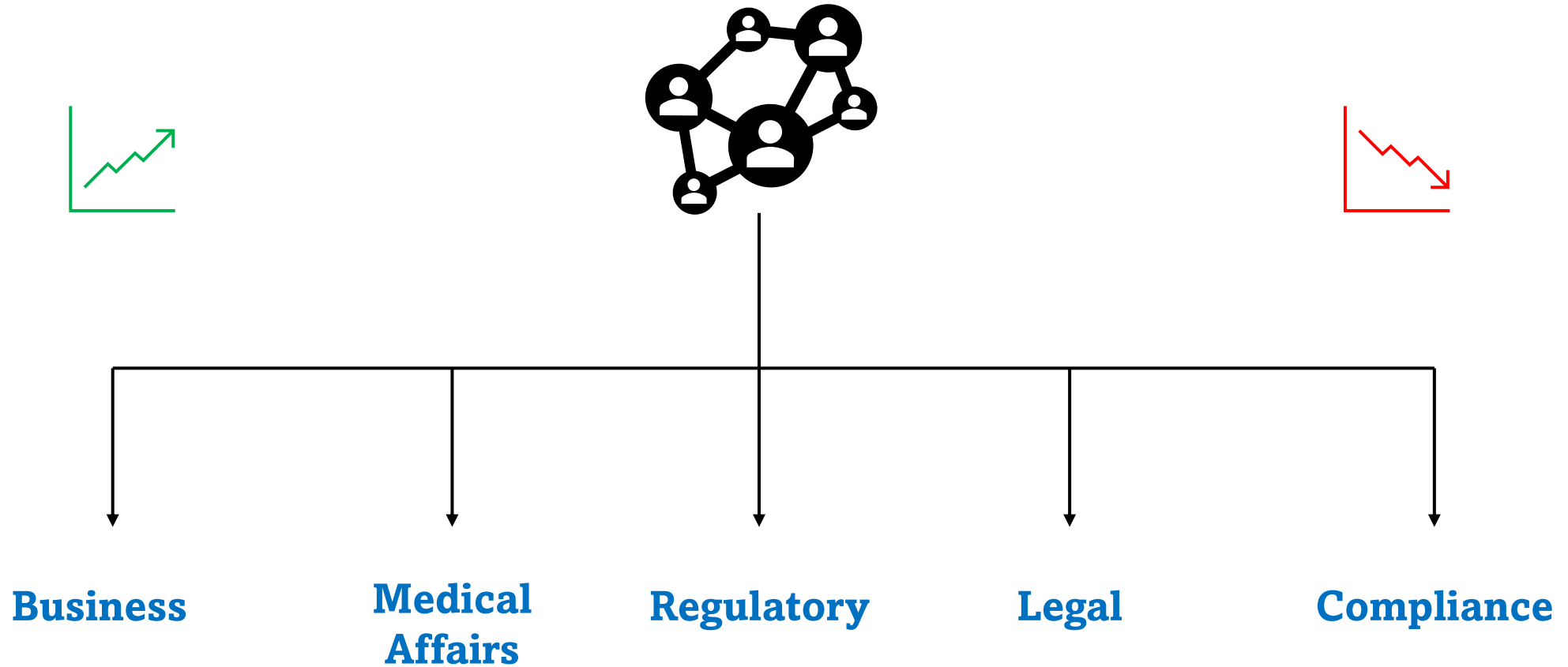


Why all external company materials must be reviewed?



- Scientific integrity
- Patient safety
- Impact on company's reputation
- Compliance
- Strategy implementation
- Avoid regulatory consequences

Review of promotional materials... A Cross-Functional work



What is the Medical Review of Promo Materials?



- To verify the scientific and medical accuracy of content as presented and ensure the quality of messages and communications.



- Content and materials need to meet legal, regulatory, and industry code as well as ethical standards.



- Medical Review must be conducted by a trained and certified person (Certified Medical Reviewer) to assess the scientific accuracy and medical validity.

Role of the Certified Medical Reviewer

- **Accurate:**
 - All content is truthful, accurate, clear, scientifically balanced, and not misleading.
- **Evidence-based:**
 - All medical and scientific statements within content are supported by reliable and appropriate scientific evidence (product label, clinical trials, etc.).
- **Compliant:**
 - All content adheres to applicable country laws and regulations, industry guidelines, your company's values and standards, and is respectful in terms of taste and tone.
- **Appropriate:**
 - Communications are appropriate based on the intended audience (e.g., Patient, HCP, or Payor).

What makes you a GOOD Certified Medical Reviewer?

Medical
Qualifications

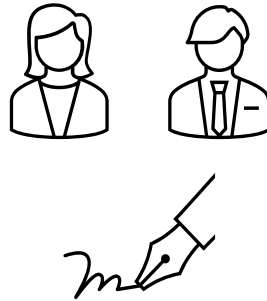
TA strategy

Company
Certification

Communication
skills

Local
Requirements

Courage and
independence



Different types of medical evidences

Product
Circular

Reputable
scientific
medical
journal articles

Textbooks,
manuals,
encyclopedias,
or dictionaries

Reputable
publications
from health
organizations

Local health
department
statements

Global/local
medical
society
guidelines

University and
hospital
publications

Established,
reputable
Internet sites

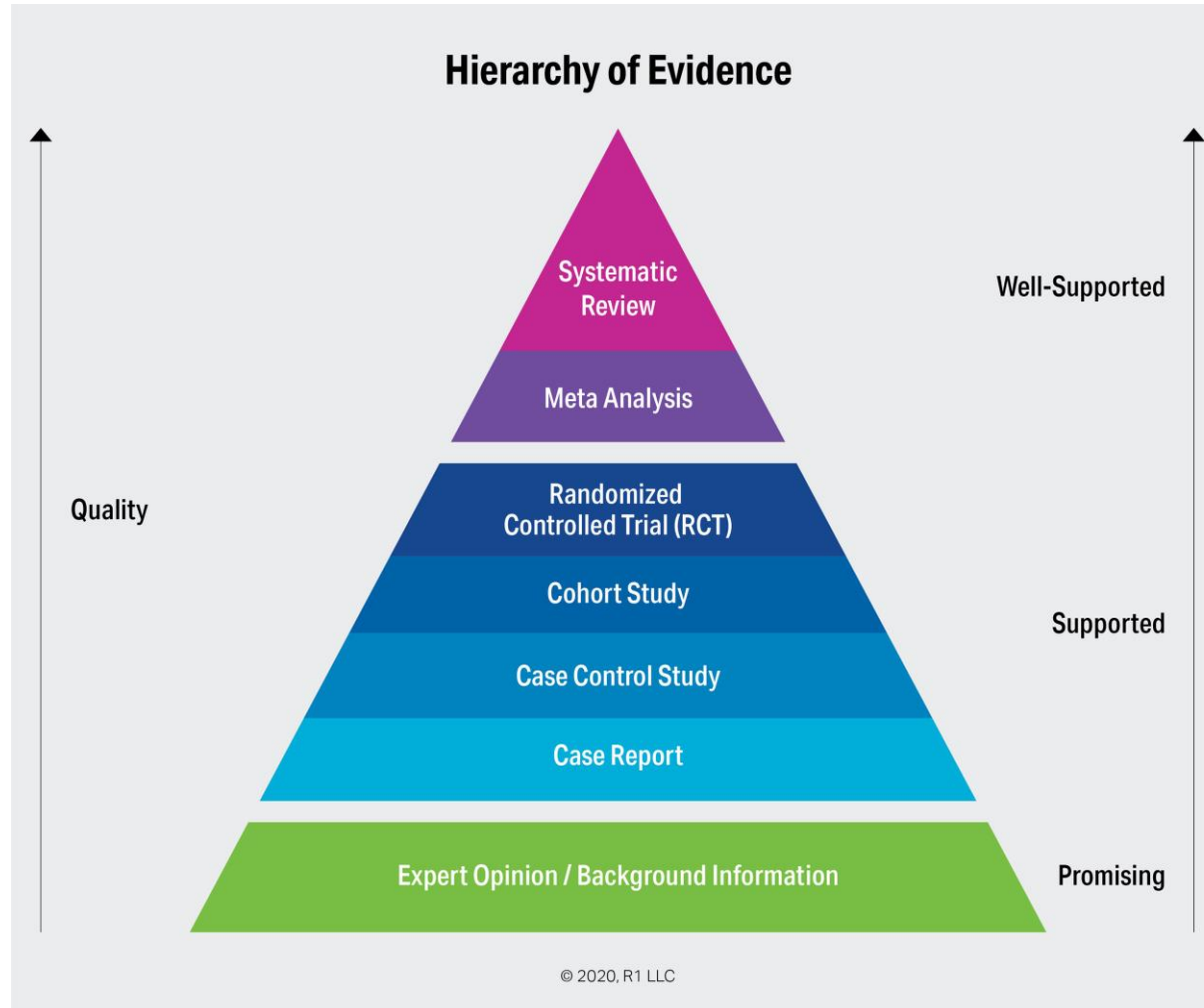
High-quality,
peer-reviewed
journals

Congress
abstracts

Approved
competitor
local Product
Circulars



Hierarchy of medical evidences



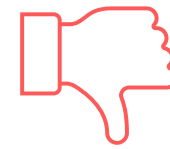
Reviewing a promo material – Check the tree first!



Practical Examples

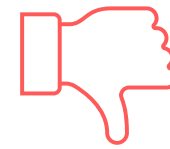
Unleash the medical reviewer inside you!

According to 2010 American Diabetes Association Guidelines for management of Type-II Diabetes Mellitus, Product X should be used as 1st line treatment followed by Product Y, Z



Always check for the most recent evidence

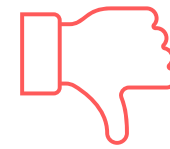
Drug X reduced CV mortality by 50% in patients with uncontrolled hypertension



This was based on a subg

Always use the primary endpoint

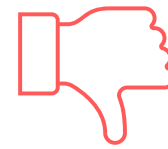
Product X proved more effective in reducing Blood pressure compared to Product Z.



Product X was superior in head-

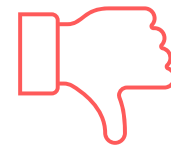
Always rely on H2H data not
extrapolations

Rota virus can kill your child, Vaccinate them Now!



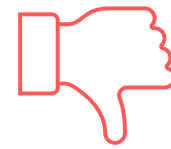
Always avoid intimidating the patient

Live your sexual life freely, The morning-after pill is here for you!



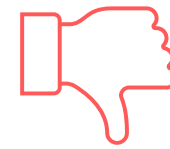
Always respect the culture

Product X achieved a huge reduction in body weight. Patients maintained weight loss for up to two years with no rebound. There was a significant improvement in the quality of life. No or minimal side effects



Always balance the information

Product X is the first-in-class, and best-in-class for the treatment of dyslipidemia



Always avoid exaggerated claims



Summary

