Lebanese Code of Ethics
A New Milestone

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What is Ethical and Unethical to Offer?

&

What is Acceptable to Receive?
What is Acceptable?

• You work in a pharma company and you have a New Drug that you are promoting
• Knowing that some of the doctors you want to target play football
• Would you offer them football socks with company’s logo on?
• Would you invite them for a trip to go watch the Euro 2016 Cup finale?
Drug Promotion

- All informational and persuasive activities by manufacturers and distributors, the *effect of which is to induce prescription*, supply, purchase and/or use of medicinal drugs (WHO)

- Can significantly influence the way medicines are prescribed, dispensed and used

- Can lead to over-prescribing and poor quality prescribing and medicine use leading to increased risks of adverse effects and higher healthcare costs
Unethical Promotion of Drugs

**PRIMARY INTEREST:**
Patient Care

**SECONDARY INTEREST:**
Independent Judgment Compromised

Employee/Agent of a Pharma Company

Secondary Interest: Personal Material Benefit

Patient

Healthcare Professional
Ethical Promotion of Drugs

• Healthcare professionals have access to accurate information about new drugs & new updates
• Patients have access to medicines they need
• Medicines are prescribed and used in a rational and appropriate manner
• Preserve independence of healthcare professionals in exercise of medical judgment
Code of Ethics for Drug Promotion

What is ethical varies from one person to another, in different parts of world, in different societies.

Ethical criteria lay foundation for proper behavior concerning promotion of medicines.

It sets standards for ethical marketing and promotion of Prescription Products directed to healthcare professionals.

Criteria will assist in judging if promotional practices related to medicinal products are within acceptable ethical standards.
What is Code of Ethics for Drug Promotion?

- Set of principles to govern all medicines marketing phases, and to monitor all parties involved in production, importation, marketing, prescription, and dispensing of medicines
- Guidelines for health professionals on how to manage their interactions with pharmaceutical industry
- Guidelines for pharmaceutical industry about how to implement marketing practices to establish transparency and accountability
Examples of Code of Ethics

• Ethical Criteria for medicinal drug promotion by WHO, 1998


• Drug Promotion Guidelines in Jordan 2009

• Gulf Code of Pharmaceutical Practices in GCC 2011

• Other Codes:
  Argentina, Australia, Austria, Belarus, Belgium, Brazil, Canada, Chile, China, Colombia, Czech Republic, Denmark, Ecuador, Finland, France, Germany, Guatemala, Hungary, India, Hong Kong, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Netherland, Norway, Peru, Philippines, Portugal, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, UK, USA
Lebanese Code of Ethics 2016

- Sets regulatory frameworks that ensure respect of legal, ethical and scientific principles in medicine market to serve patient as well as medical and pharmacy professions in Lebanon

- Aims to enhance rational use of medicines and to prevent all practices that do not comply with ethics by providing a reliable reference to marketing practices and a clear monitoring and implementation mechanisms
To Whom Does Code Apply?

- Physicians
- Dentists
- Pharmacists
- International Pharmaceutical Companies & Scientific Offices in Lebanon
- Members of Pharmaceutical Importers and Wholesalers Association
- Members of Syndicate of Pharmaceuticals Manufacturers
- Members of Syndicate of Private Hospitals Owners
- All parties involved in marketing & promotion of medicinal products and who do not belong to any of above parties
Components of Code

I. Marketing and Promotion Practices
• Promotion
• Advertisement to Public
• Promotional Items and Gifts
• Medical Samples
• Congresses and Symposia
• Scientific Research
• Post-Marketing Studies
• Contracting with Healthcare Professionals
• Grants and Donations
• Patients Associations
• Medical Representatives

II. Implementation Procedures
• 2 committees
• First Level, Second Level, Third Level
Promotion

- Active promotion targeting health professionals should only be with respect to Drugs that are registered in Lebanon.

- Promotional claims should be reliable, accurate, informative, balanced, up-to-date, and in accordance with package inserts; promoting off-label is Not allowed.

- Medical and scientific body can be informed about medical progress through appropriate tools and methods, provided that scope is Not promotional.

- **Advertisement to Public:** direct-to-consumer advertisement is prohibited by law.
Promotional Items and Gifts

• Gifts with modest or symbolic value are allowed provided:
  - 10% of monthly minimum wage (≈50$)
  - Related to drug promoted
  - It is beneficial to patient care
  - Directly related to professionals’ practices

• Items useful for profession may be provided:
  Books, medical and scientific magazines, subscriptions in scientific publications, anatomical models, diagnostic tools, …
Promotional Items and Gifts

- Cash payments, direct or indirect are considered as bribes and are illegal
Medical Samples

• In accordance with pharmacy law, Free samples of a pharmaceutical product may be supplied to Physicians & Dentists

• Samples should be provided in moderate quantities and should NOT be resold

• Adequate system of control on free samples, including how they look and permanent print:
  “Free Medical Sample, Not for Sale” on inner container if possible and on outer package in Arabic and/or any other language
Congresses and Symposia

- **Type I**: Congresses aiming at providing scientific and educational benefits to professionals
  - Include scientific and educational activities undertaken by health professional associations, scientific societies, and health institutions inside or outside Lebanon
  - It is NOT allowed to mention Brand names
  - CME can be offered and relevant professional order will be responsible for content
  - Sponsors can present promotional materials such as banners outside congress halls
Type II: Congresses and symposia that fall within scope of advertising and promotion for a particular medicinal products

Information related to promoted medicinal products should be in reference to indications approved by international agencies such as EMEA and FDA

No CME to be offered
Congress and Symposia

- Coffee breaks, lunches and dinners should not exceed 25% of total time of event
- Congress/symposium should not include sponsoring of recreational activities (sports or entertainment)
Congress and Symposia

- Sponsors can contribute to travel, accommodation, meals, and registration fees of participants.

- It is prohibited to pay expenses for families and accompanying persons who are not directly related to event.

- Sponsors should present to concerned professional orders periodically programs of events and activities they sponsored.

- They should also inform concerned order of names of doctors and/or pharmacists who participated in these activities.
Scientific Research & Post-Marketing Studies

• **Scientific Research:**
  - Should not be used at any of its stages to promote any medicine and should be subject to current regulations and laws

• **Post-Marketing Studies:**
  - Should not be masked promotion and of scientific purpose
  - Should obtain prior approval of IRB of health center based on a written proposal
  - There should be a written contract between company and professionals or participating institutions and fees subject to applicable local standards
Contracting with Healthcare Professionals

• It is permitted to contract with healthcare professionals, as individuals or groups, for a fee, to carry out scientific activities.

• Exclusivity is not allowed.

• Contracts should be signed before initiating activities.

• Fees should be applicable to local standards.

• The consultants should disclose to others when needed the relationship with contracting company.

• The concerned professional orders should be notified by companies of names of consultants and contracting subject.
Grants and Donations

- Donations and grants are limited to scientific institutions or charitable and professional organizations that provide healthcare, and/or that conduct scientific research.
- Donations are to institutions, not individuals.
- Be documented in records of both donor and recipient.
- Not be used as a mean for increasing purchases of pharmaceutical products of donor company.
Patients Associations

• These associations should be officially registered as non-profit patient associations

• Support should be documented in a written agreement describing nature and purpose of support

• Support should be publicized in full transparency

• Exclusivity is not allowed
Medical Representatives

• All companies are responsible for providing medical reps with appropriate training to give them sufficient knowledge to provide information about medicines in an accurate, responsible, and ethical manner

• Medical representatives should respect applicable laws and regulations
• Behave professionally during visits to health institutions
• The salary of medical rep should not be directly related to sales volume achieved
Information Disclosure

- Medical representatives should provide complete information on contra-indications & side effects of drugs.

- Pharmacists working in private/hospital pharmacies are NOT allowed to disclose any information related to physician’s prescribing patterns UNLESS it is requested by relevant orders/MOH in context of an official investigation.

- For Post-Marketing Studies; confidentiality of information should be respected & Results should be disclosed to all participants.
Implementation Procedures

1- Monitoring

- A professional supervision committee لجنة الاشراف المهني to oversee implementation of Code and include representatives of:
  - Order of Physicians in Beirut & North, Order of Dentists (1 member each) & Order of Pharmacists (2 members)

- Duties:
  - Monitoring promotion practices and impact on professionals
  - Review documents related to congresses sponsored by companies and contracts made with professionals
  - Reviewing complaints of violation of Code
  - Following up on implementation
  - Coordinate with Pharmacy Inspection Department at MOH
2. Review Procedures & Deterring Violations

- **First Level:**
  - Professional supervision committee will send complaints received to violating company, scientific office, or importer
  - Complaint will be sent in writing and include content of violation with available documents and will be given 20 days to respond
  - Committee will immediately inform concerned professional orders to take appropriate measures against offending member
  - A copy to be sent to Pharmacy Department at MOH
• Second Level:
  - If response is not satisfactory or a solution cannot be reached, committee should file a written complaint with documents to:
    - Parent company abroad
    - International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
    - PhRMA Middle East and Africa (MEA)
    - MOH
    - Review Board
The review board is to be established by a ministerial decree by Minister of Public Health as follows:

- Director General of Ministry of Health
- Head of Order of Pharmacists in Lebanon
- Head of Lebanese Order of Physicians in Beirut
- Head of Lebanese Order of Physicians in Tripoli
- Head of Lebanese Order of Dentists
- Head of Lebanese Pharmaceutical Importers and Wholesalers Association
- Head of Private Hospitals’ Owners Syndicate
- Head of Syndicate of Pharmaceuticals Manufacturers in Lebanon
- Chair of Group of International Pharmaceutical Companies in Lebanon
- Head of Pharmacy Department at Ministry of Health
- Head of Inspection Department at Ministry of Health
- Head of Health Promotion Department at Ministry of Health
- Legal Expert appointed by Ministry of Health
Review Board

- Review board should communicate with concerned parties, complete review, follow up on result of complaint, and issue a recommendation within a period of 40 business days.

- Correspondences and deliberations will be kept confidential as well as identity of parties involved.

- If response is unsatisfactory, recommendation shall be referred to third level.
Review Procedures & Deterring Violations

• Third Level:
  - Review Board submit recommendation to Minister of Public Health to take appropriate action

• Complaints that reach this level will be publicized and confidentiality will be lifted of file including identity of parties involved
Pledge and Signature

• The Code was launched under Patronage of Prime Minister H.E Mr. Tamam Salam from Grand Serai on May 31, 2016

• All relevant parties emphasized their voluntary compliance with Lebanese Code of Ethics, and adherence to all its clauses and to adopt transparency, discipline, and self-control as a basis for its proper application

• All relevant parties signed
What is Acceptable & Not Acceptable Based on Code?

- Personal Gifts like jewelry
- Recreational Activities (i.e. golf, tickets to sporting events, concerts, vacations packages, etc.)
- Lunches/Dinners not in connection to an event
- Company paid for Musical Performance during dinner during a conference
- Cash Incentives
- Office Equipment
- Expensive Electronic Items
- Furniture
- Renovation of Clinic
- Invitation to Social Event
- Paying for a Guest/Companion
What is Acceptable & Not Acceptable Based on Code?

- Items of Medical Utility
- Hosting Scientific and Promotional Meetings
- Antibiotics Guide
- Conference with Lunch
- Dinner with Lecture
- Scientific Article
- CME
- Pen
- Mug
- Flowers
- Cultural Courtesy Cards/Gifts

Inexpensive Courtesy Gifts not related to Medical Utility
What is Acceptable & Not Acceptable Based on Code?
Last Words

Implementation of the code is a matter of Self-Regulation & Self-Discipline

FOR THE CODE TO BE MEANINGFUL, NEED YOUR SUPPORT
Thank You