



نقابة صيادلة لبنان
Order of Pharmacists of Lebanon

Towards a National Pharmaceutical Strategy in Lebanon

Appendix C – Final Implementation Plan for the Code of Ethics

A project by:
The Order of Pharmacists of Lebanon



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Implementation Plan for the Lebanese Code of Ethics

A. The Lebanese Code of Ethics covers the following types of products:

- Pharmaceuticals including prescribed and OTC drugs
- “Pharmaceutical-like” (بحكم الدواء)
- Milk Formulas for Infants & Babies up to 2 years
- Food supplements cannot be included under this code of ethics as it falls on a different law (Decree No. 5518 issued on December 14, 2010 المتعلق بالمنتجات الغذائية و المنتجات الطبيعية ذات الفوائد الصحية); can recommend to MOPH and the relevant committee responsible for this file to develop a similar code of ethics to this one or adopt this one and be in line with the law.

B. Pharmaceutical Industry includes:

All parties involved in the marketing and promotion of medicinal products in Lebanon

All pharmaceutical companies and “scientific offices” representing pharmaceutical companies operating in Lebanon, importers, wholesalers, and local manufacturers.

C. Healthcare Professionals include:

Physicians (including medical students, interns and residents), dentists and pharmacists and other healthcare professionals

D. Monitoring and Review Procedures and Deterring Violations:

- Need to re-establish by a ministerial decree the professional supervision committee consisting of one member representing each of the Order of Physicians in Beirut & North, the Order of Dentists, and two members representing the Order of Pharmacists.

This committee is responsible for:

- Monitoring promotion practices and impact on professionals
- Receive annual reports from all pharma about their activities and contacting with professionals
- Development of standardized/unified forms to be used for reporting from industry and for complaints
- Set email address to receive complaints

Electronic database for submission to be considered: it is not a must, optional to consider if resources are available: Recommendations to be developed further as it requires resources: financing, logistics, web hosting, and cloud-based among others. Can look for similar databases for best practices. Ensure confidentiality agreement is signed.

- Reviewing complaints of violation of Code
 - Following up on implementation
 - Coordinate with MOPH
 - Meet on regular basis (to be decided) and when needed
- Need to re-establish the review board also by a ministerial decree and this board should include the following members/entities:



- 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 Procedures and Deterring Violations: three levels are proposed to be followed by the Lebanese Code of ethics:

For the first level:

- **Optional: company to company resolution within 15 days and if not resolved inform the supervision committee.**
- Supervision committee will investigate complaints
- Send to violating company, scientific office, or importer
- Complaint will be sent in writing and include the content of violation with available 2 documents and will be given 20 days to respond
- Committee will immediately inform concerned professional orders to take appropriate measures against the offending member
- A copy to be sent to MOH

For the second level:

- If the response is not satisfactory or a solution cannot be reached, the committee should file a written complaint with documents to: Parent company abroad, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), PhRMA Middle East and Africa (MEA), MOPH and to the Review Board
- Review board should communicate with concerned parties, complete review, follow up on the result of the complaint, and issue a recommendation within a period of 40 business days
- Correspondences and deliberations will be kept confidential as well as the identity of parties involved
- If the response is unsatisfactory, the recommendation shall be referred to the third level
- For levels one and two, investigations will be kept confidential

For the third level:

- Review Board submit a 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



E. Reporting Requirements by Pharmaceutical Industry should be done on:

- All types of sponsoring congresses/symposia that target healthcare professionals mentioned in the code of ethics inside and outside Lebanon should be reported. These include Educational Conferences & Promotional meetings of congresses and symposia among others.
- Contracting with healthcare professionals inside Lebanon. Contracting with healthcare professionals who are based in Lebanon for outside activities need also to be reported (contracted for an event abroad for example).
- Donations/grants to institutions/organizations mentioned in the code
- Funding patients' associations/organizations
- Donations/grants to academic and research institutions
- Reporting to be kept to a minimal level to ensure confidentiality yet allow oversight on activities conducted to ensure adherence to the code of ethics.

F. Frequency of Reporting:

- End-of-year reporting during December for all activities conducted (as detailed in section E above).

G. Start of Implementation: 15 December 2023

H. Reporting Structure/Content of Submission:

All reporting is to be done using a standardized form with checklists to be developed at a later stage by the supervision committee to be formed.

For all types of congresses, symposia, conferences, and meetings done inside and outside Lebanon, the following relevant information should be reported:

- Type of Congress/meeting, name/title, venue, date, type of participation, and sponsorship (booth, symposia, printing material, promotional material provided, and others).
- If HCP are sponsored, then specify the total number covered and what was covered: accommodation, travel, registration fees, sponsoring meals,
- Organizing or sponsoring events outside Lebanon is allowed as per the Lebanese code of ethics. Companies operating in Lebanon (local or International) organizing or sponsoring an event or participation of healthcare professionals (from Lebanon) outside Lebanon, to respect the Lebanese code of ethics related to organizing/sponsoring an event.
- Also submit the name of the countries where the events took place in addition to the information requested above.
- Given that all criteria related to
- All venues selected should be conducive to business and not known for recreational or leisure activities.

For Contracting with Healthcare professionals:

- The reporting should include the total number of contracts done with HCPs, per therapeutic area, type of services/engagement to be provided, duration of consultancy/contracting (if applicable)



- The contract should include a provision regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. The contract should also clearly state that the contracting with the healthcare professional is not exclusive and fees paid are based on fair market value.

Donations/Grants:

- Reporting should include the total number of donations, grants, and benefits-in-kind made for institutions/organizations/associations mentioned in the code: including the type of institution receiving the donation and the type of the donation.
- The contract should include a clause that the donation does not constitute an inducement to recommend, prescribe, purchase, supply, sell, or administer a specific medicinal product.

Patient Associations:

- Reporting should include the total number of supports provided to patient's associations and per entity with the scope of work of the patient association (without the names): including the type of support (medicine, educational materials, educational meetings, testing, etc.) and summary of activities agreed to be carried on as part of the funding.
- The contract should state that the company does not require being the sole funder for the patient organization or any of its major programs. In addition, the contract should state that any activity done within the agreement should not include direct advertisement to the public or promotion of specific pharmaceutical products. The support should be provided to a patient association/NGO officially registered at the ministry of interior or have another legal existence in Lebanon.

Research:

- Research reporting to include reporting on post-marketing studies, Phase VI only (i.e., excluding clinical trials done as phases I, II, III).
- Reporting should include the type of research per product and the type of institutions contracted to conduct the research.

Media:

- Report on activities done with all types of media. Medication promotion is not allowed in Lebanon based on the pharmacy law dated back to 1994. This is related to disease awareness campaigns conducted by the pharma industry. Reporting to include total number and type (Ad board, AV, ...) and per targeted diseases. Activities with media are to be aligned with Ministerial Memo number 131 issued by MOPH on 24 December 2019 on disease awareness using all media channels.

I. Reporting should be done directly to:

- Relevant committee members from the supervision committee representing one of the four orders (to more than one if needed) will be responsible to receive, review, and briefing/share with other committee members.
- Reports should be sent via email address to the concerned person in each order (password protected), or to web-centered filing addressed to the concerned person in each order and



labeled as CONFIDENTIAL and to be sent once per year (as stated above) to the relevant orders. To ensure that there is no leakage beyond the relevant committee

- Pharmaceutical companies should receive confirmation of recipients.
- All reporting will be kept confidential and not for publishing purposes. It will be kept under secure lock for 3 years from the date of reporting.

J. Pharmaceutical Industry (defined above) Responsibilities:

- Sign/re-sign the pledge of the code on yearly basis
- Inform and remind all staff/employers about the code components
- Provide comprehensive training on the code
- Regular reporting
- Answer and justify complains with evidence
- Distribute copies of the code of ethics to medical societies
- Sign on Read and Understood

K. Responsibilities of Professional Orders:

- Sign/re-sign the Pledge of the code with every new head and board of orders
- Inform all registered members in an appropriate way and newly joint members
- Sign on Read and Understood
- Provide lectures if needed
- Provide copies of the code to organizers to ensure compliance during CME-related events and ensure distribution of the code during scientific/educational conferences (Obligation of Lebanese order of Physicians and Order of Pharmacies)
- Assigned person **part of the committee** to Review reporting from industry via review supervision committee
- Follow up on complains against their members
- Ensure confidentiality of complaints investigations at first and second level.

L. Complaints received should include the following to be processed:

- Include name and contact details of the person submitting the complaint
- Name of violating company
- Name of violating healthcare professionals if applicable
- Sufficient information with physical evidence on violation (copy of advertisement, pictures of events, etc.).

If the complaint cannot be validated, it will not be processed.

A standardized form to be prepared.

M. Social Media Advertising

This is in line with Memo number 131 issued by MOPH on 24 December 2019 on disease awareness using all media channels including social media.



Running any disease awareness campaign or activity related to addressing citizens directly or indirectly through social media networks must be subject to the following:

- Be granted pre-approval from the Ministry of Public Health, as a written request must be submitted.
- The request shall include detailed information on the campaign or activity
- It is forbidden to use campaigns (and any educational material disseminated) as a form of advertising for a medicinal product through social media networks
- A standard template for educational materials (size, font) shall be adhered to, as part of coordinating with the relevant departments at the Ministry of Public Health
- The logo of the Ministry, as well as its email and hotline number 1214 shall be presented on all educational materials used during the campaign on social media. The logo should be 20% bigger than all other logos and should be placed at the top center of the page.
- Any pharmaceutical company that intends to set up an activity or campaign through social media platforms should cooperate with one of the scientific societies, orders, hospitals, non-governmental organizations, and universities
- Media Coverage of any activity within the scope of promoting a specific drug and targeting health workers such as doctors and others through any means of social media is strictly prohibited. The latter counts as a direct advertisement that targets the audience (patients/public) and thus conflicts with the pharmacy profession law and practice, as well as the code of ethics for medicinal products promotion in Lebanon.

N. General Clarifications:

- Companies operating in Lebanon are obliged to follow this code of ethics; they can however follow a stricter code of ethics if it is based on their organizational requirements.
- Promotional guidelines of this code of ethics apply to all communication channels including all oral and written communications, in addition to websites and social media.
- Promotional material targeting HCP (like notepads, pens, calendars, etc.) can include the name and logo of the company and the trade name or INN of the medicinal product. Companies are free to follow stricter guidelines.
- Sponsoring the participation of healthcare professionals in events outside Lebanon can include travel expenses, accommodation, registration fees, and meals. Per diem subsidies are not allowed.
- No payments are allowed to compensate healthcare professionals for time spent attending an event.
- Sponsoring education conferences/congresses/symposia:
 - Should in no way be tied to control by the sponsor over the selection of content, faculty, educational method, materials and venue. This to be done in agreement between sponsor and the academic entity.
 - Sponsorship should be disclosed to attendees prior to and during an event in brief statements on conference materials such as brochures, syllabi, agenda, poster sessions, or any other appropriate means. Thus, the Logo of sponsor companies is allowed to be used as an



appropriate recognition/acknowledgment for support but using logos/names of drugs is NOT allowed.

- Using promotional aids (like notepads, pens, etc.) that hold the logo of the sponsor company inside the conference is allowed. It is NOT allowed to use such material that holds a brand name of a drug.
- Can include financial support for meals or receptions to all attendees.
- Sponsors can present ONLY as promotional materials such as banners/roll-ups outside congress halls (Hall/Reception Area) if the conference/event is granted CME.
- Presenting results of Bioequivalence studies where there is a need to mention brand names can be done under Type II of Congresses and symposia mentioned in the code that falls within the scope of advertising and promotion for particular medicinal products where CME is not granted.
- It is allowed to have a session within a scientific conference where a brand name is mentioned, but NO CME should be given to that session.
- Media coverage and press releases:
 - Press releases related to national campaigns, Media education sessions (where media attends education sessions about disease overview and generic treatment protocols, etc.) are acceptable practices.
 - Press releases informing the media and the public about new medications becoming available by being locally registered, press releases about new medications receiving FDA or other approvals, and press releases about the launch event of a new medication and attended by healthcare professionals are not acceptable as they represent direct advertisement to the public and this is prohibited by the Pharmacy Law.
- Promotional Items and Gifts like:
 - Cultural and courtesy gifts (like chocolate, and flowers) are allowed on certain occasions for example on Christmas/Easter/Eid Occasions as this is part of our Lebanese culture as long as the gift has a cap per the code of ethics not to exceed 10% of the current minimum wages of HCP.
- Sponsoring a sports event at the national level is allowed as long as it does not include any advertisement for any drug (neither Brand nor Generic), only the name of the company will be allowed on promotional material.
- Printed copies of the code of ethics to display during congresses and symposia should be made available and it will be the responsibility of the sponsors to print the needed number of copies or make them available on CDs or through QR code (can be added on the program of the congress). This should be the responsibility of either the medical societies, professional orders, or event organizers.
- In the code it says: "in line with the content of the Code of Ethics for Medicinal Products Promotion in Lebanon" shall be clearly placed at the beginning of each congress or symposium." Clearly placed" means: this sentence should be placed either on the banners or on the projected slides at the beginning of the conference, between sessions and when appropriate. In addition, to having either hard copies of the code or copies made available as soft copies during conferences. This should be only once in the opening session of the congress.



O. Other Activities Not covered by Code: need to develop specific guidelines:

- Websites that are targeting the public should follow the same restrictions of this code of ethics as it is considered a promotional channel.
- Mobile apps
- Sending SMS & emails (sending SMS and individual messages to HCP strictly is acceptable given that consent should be collected prior to sending SMS or individual messages. Sending SMS and emails to the public is NOT allowed.
- Use of celebrities/spoke persons to talk about medications
- More guidelines are needed for use of social media advertisements/awareness campaigns

A general recommendation is to Update the Lebanese code of ethics when possible; but this not to delay the enforcement of the current one that is endorsed by all relevant parties.

References:

1. Lebanese Code of Ethics - 2016.
2. The Middle East Africa (MEA) Local Area Work Group (LAWG)-Code of Promotional Practices- 2021
3. International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Practice-2019