LPIA
SINCE 1948

HORIZON 2030

Executive Summary
LPIA Workshop
30th September 2017

CONTENTS

1.0
INTRODUCTION

1.1 The Event & Objectives

LPIA workshop Horizon 2030 at Hotel Al Bustan on 30th September 2017.
The Objectives

- To communicate
- To initiate a brainstorming
- To end up with a list of recommendations

1.2 The Agenda & Presentations (Sent separately to all attendants)

- The Dynamics of the Pharmaceutical Sector
- The Regulators & Sales to MOH
- The Professional Associations
- The Media/Communication Plan
- The relations among LPIA members
- The Future of the profession of "Importers/Distributors"

1.3 The Attendance

- 28 companies
- 53 attendants
- CEOs (20), Executive Directors (12), Regulatory/Quality Managers (12), Sales & Distribution Managers (9)

2.0
THE PROFESSION

2.1 Role of the Importer/Distributor

The Importers/Distributors constitute a precious and critical link between **Lebanon** and the **global** pharmaceutical industry, whether their production is innovative and research-based **(R&D)**, or covering Generics that are legally copied from the originals.

On behalf of the pharmaceutical industry, the Importers/Distributors have responsibility for the quality and prices of their imported drugs. They will always seek to make available to Lebanese Patients and the Lebanese Medical Community the most **advanced Medicines**.

The **responsibility** and **continuity** factors are an essential part of the Importers/Distributors' role. Committed as they are to their principals, Patients, health-care professionals and the local authorities, they ensure a consistent and **sustainable market supply**.

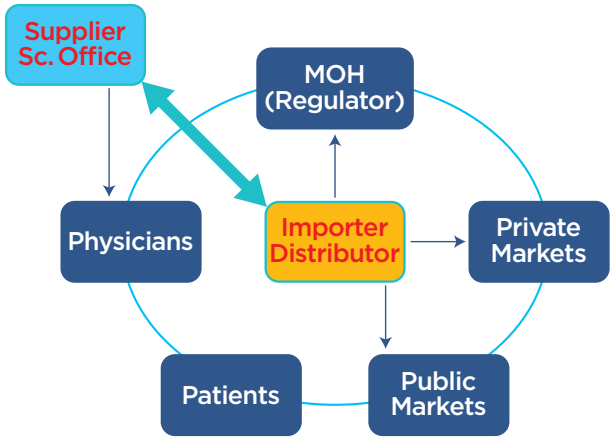
2.2 Exclusivity: obligation or privilege?

Product Exclusivity in the pharmaceutical sector is not a privilege without consequence for an Importer/Distributor. On behalf of the companies they represent, it comes with an obligation to take **unbroken responsibility** for the **quality** of imported pharmaceuticals from the **producer** to the **citizen**.

2.3 Firm conviction

Complex and fast-moving issues within the Pharmaceutical Sector need to be dealt with responsibly by all concerned parties in the private and public sectors. A regular update of regulations is required to accompany the important and fast developments of the Industry and to ensure reliable quality and supply of pharmaceuticals at fair prices.

3.0
THE BUSINESS MODEL



SOURCE OF SUPPLY

- **Manufacturer of Pharmaceutical Product**
- **Marketing Authorization Holder**
- **The responsible Party**
- **The "Producer" المنتج**

PRODUCTS	REGULATORY	ACCESSIBILITY	ACTIVITY	RESPONSIBILITY
API	Registration conditions	For a given R&D based manufacturer, giving a country like lebanon an **"early access to its innovative medicines"** implies huge investments and costs including: local clinical trials, market assessment of the country benefits from using the medicine, designing the appropriate scientific information to be spread among healthcare professionals, educating the human resources who will be empowered to spread the information, selecting the target audience of doctors and pharmacists who will be involved in prescribing and dispensing the medicine, setting the right shipping, storage and distribution conditions through a well-selected importer/distributor, designing support plans to patients, third party payers and public institutions.	Registration	Manufacturer/ MAH/Importer
Originators	Bioavailability			
Generics	Bioequivalence			
Biologicals	Biosimilarity			
Biosimilars	Re-registration of imported generics + limitations		Pricing	Manufacturer/ MAH/Importer
Patient designed drugs	Pricing conditions			
Orphan drugs	International pricing comparison (IPC)			
	Re-pricing			
	Pricing alignment			
Pharmaceutical like	Registration conditions			Manufacturer/ MAH/Importer
Food supplements				
Transversal to all products	Code of pharma promotion		Medical promotion	Manufacturer/ MAH/Importer
			Prescription	Doctor
			Post marketing surveillance	Manufacturer/ MAH/Importer
	GSDP	Unbroken chain of responsibilities from producer to citizen	Importation	Importer
			Warehousing	Importer
			Distribution/ sales/collection	Importer
			Distribution/ sales/collection	Wholesalers
			Delivery to patient/ collection	Pharmacies hospitals
	Special conditions to dispensaries + limitation to generics		Delivery to patient free	Dispensaries
	Lobbying of the local industry to preferential treatment by public institutions		Delivery to patient free	Public institutions
			Payment	Patient/ 3rd party payers

4.0
CHALLENGES

4.1 At the level of each Importer/Distributor

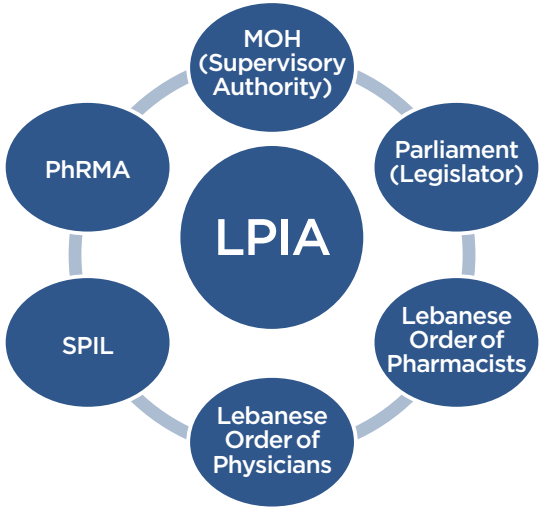
- **Regulatory:** Hard regulatory environment. New decisions are coming through that delay submissions and affect product pricing. The Importer/Distributor, being a major stakeholder, must have a direct involvement and give their opinion before issuing any new legislation.
- **Suppliers:**
  - Manufacturers want at the same time: product availability, maximum market share and lowest risk/cost sharing.
  - Discontinuation of products due to low prices while MOH is asking not to discontinue products even if their price level became below floor price.
- **Third Party Payers:** Request from Importers/Distributors and Manufacturers to offer market access programs with NSSF and MOH (PSP,...) for expensive medications while staying compliant.
- **Market Practices:**
  - Uncertain promotional practice even after the implementation of the Lebanese Code of Ethical Promotion although complying with this code is crucial for fair competition for both pharmaceuticals and food supplements.
  - Need to identify legislations governing the use of media platforms by pharmaceutical companies and syndicates.
- **Market Needs:**
  - Secure continuous supply of products and introduction of innovative products despite all the difficulties and the current economic environment.
  - Assure integrity and quality of products.

4.2 Interactive and beneficial cooperation and possible consolidation

- Study possibility of setting a “disciplinary system” between LPIA members. LPIA board to be the “Judge” or a source of arbitration to resolve conflicts between members and non-members.
- Draw the line between what must be done for sales target while staying compliant.
- Be open to consolidation among various companies looking after competitive and efficient quality/cost ratios.

4.3 Collective action through

Work on building and strengthening LPIA corporate image and enhancing the social responsibility of the profession in front of the public and political opinion.



5.0
LPIA OBJECTIVES & VISION

5.1 Objectives

Since its foundation, LPIA main objectives have been and are still:

- to establish and update the **Practice rules** of the pharmaceutical Importers/Distributors profession
- to urge **Members** to take full responsibility of their dealings with society and its citizens, according to fully transparent rules.
- to highlight the important role of the pharmaceutical Importers/ Distributors to supply the Lebanese market with pharmaceuticals of unquestionable quality at regulated and reasonable prices, insuring the **public interest**.

5.2 Vision

Innovative Healthcare Solutions

- **Maintain "First wave" launching**
  For a small country like Lebanon with a market size that may not be attractive to Multinational companies, it is important to ensure that our regulatory system and environment is progressive and values new innovations. An overly restrictive, bureaucratic, slow review process and rigid pricing regulations will only delay access, impacting patients on the short run and the overall healthcare system on the long run.
- **Fast Track Regulatory Approvals**
  Fast Track approval process for new innovative medicine with high unmet medical needs and designated by FDA/EMA as Fast Track.
- **Fair Pricing System**
  Pricing system needs to be fair and not restrictive to avoid companies defer their regulatory submissions in Lebanon until after all markets have launched.

Cooperation with foreign/local generic companies
To ease the burden of the pharmaceutical bill by encouraging high quality/ low price products.

Creativity & Cooperation with regards to the future of the profession of Importers/Distributors

Strengthening the corporate image of the profession

6.0
LPIA AD HOC COMMITTEES

LPIA Board to create one or more of the following Ad Hoc Committees that will operate according to an agreed "modus operandi" including head of committee, rapporteur, regular meetings, agendas and Minutes, to be in constant communication with the Board.

1. Registration: Continuous update of the laws and regulations on the registration, pricing, importation, marketing and distribution of pharmaceuticals in order to keep up with the continual developments in the pharmaceutical industry internationally and locally, in collaboration with the Ministry of Public Health and the Lebanese Order of Pharmacists and the two Lebanese Orders of Physicians.
2. Pricing (in close coordination with PhRMA): Better understanding of the international pricing system of the multinationals. To reach a consensus on what should be a "fair" pricing.
3. Local Manufacturing vs. Originators & Imported Generics (in close coordination with PhRMA & SPIL).
4. Public-Private Partnership: Setting a basis for a strong and fruitful public/private partnership, taking into consideration international professional criteria and aiming at consolidating the relation between the public sector and the pharmaceutical manufacturers (Originators and Generics). (in close coordination with PhRMA & SPIL).
5. OTC, Pharmaceutical-Like, Food Supplements, Medical Devices: implications on registration, pricing, distribution channels, Advertising.
6. Market issues: Dispensaries, Trade Offers, Code of Ethics, Price compensation, expired products, Bar Code, Smuggled & Counterfeited products.
7. Relations with OPL Ordre des Pharmaciens du Liban.
8. Media and communication strengthening LPIA corporate image.
9. Deliveries to MOH w/o Funds Booking.
10. Future of the profession: From traditional distribution that will require more and more standardization to better control the supply chain and minimize cost as much as possible. - possible mergers to cope with simple services... To higher and more sophisticated patient-centered services to enable us to serve patients in need of advanced but expensive, sophisticated, biological medicines.

7.0
LPIA STRATEGIC THINK TANK (STT)

To be nominated by LPIA Board to assist in LPIA vision & action.

8.0
LPIA LOGISTICS

Developing LPIA Office space, Administrative Set-Up, Data Base and Website to support LPIA Board actions.

نقابة مستوردي الأدوية
و أصحاب المستودعات في لبنان
SYNDICAT DES IMPORTATEURS DE MEDICAMENTS
ET DES DROGUISTES AU LIBAN
LEBANESE PHARMACEUTICAL IMPORTERS
& WHOLESALERS ASSOCIATION

Badaro Street - Moyen-Orient Bldg.
P.O.Box 11- 5051 - Beirut - Lebanon
Tel: (961) 1 388 743 - Fax: (961) 1 390 958
E-mail: lpia@inco.com.lb
Web: www.lpialebanon.com