

Key changes in Ownership of Pharmacies and new Operation Framework – Liberalization of OTC Medicines



Sofia Aggelou, PhD-LLM

Legal Counsel Attica Pharmacists Association (FSA)



AGGELOU LAW FIRM
ATTORNEYS & COUNSELORS AT LAW

2nd SFEE Congress, 8.3.2018
Pharmaceutical Law and Ethics

Liberalization in Ownership of Pharmacies and liberalization of Over-the-Counter Medicines

INCIDENTAL TO:

- ▶ The obligations arising from the Memorandum (OECD Toolkit I-III)
- ▶ Modern international attitudes on abolishing barriers on protected professions

TARGET:

- ▶ Reduction of pharmaceutical expenditure-relief burdens of EOPYY caused by:
 - ✓ overconsumption of medicines
 - ✓ promotion of non generics

REASON:

- ▶ Pharmacists monopoly on medicines



Established case-law



European Court

C-171, 172/07:

“National provision restricting the right to operate and exploit a pharmacy to pharmacists alone is compatible with the Treaty, once it views to the ensuring that the provision of medicinal products to the public is reliable and of good quality.”

(related: C-268/15)

Council of State as a full Court

229/2014, 421-424/2014:

“The profession of the pharmacists is tightly bound up with the protection of public health ...and the guaranteeing of the future viability of pharmacies ...beyond rules of free competition, constitute overriding reasons relating to the public interest, which justify the imposition of restrictions...”

*(related: **1804/2017**, 2204-2224/2010, 196/2013)*



AGGELOU LAW FIRM
ATTORNEYS & COUNSELORS AT LAW

5th Depart. Of Council of State

(opinion no. 28/2018)



*"Each Member State regulates the establishment and operation of pharmacies, in a way **that corresponds to the current priorities** between the sector of economy and the sector of health...the new Presidential Decree provides adequate guarantees for the preservation of the public health".*



AGGELOU LAW FIRM
ATTORNEYS & COUNSELORS AT LAW

The Presidential Decree provides for....

(according to art. 64 par. 1 of Law 5409/2017)

Under the condition of satisfaction of the population criterion (1:1.000)

- I) Right of **any citizen of the EE to be granted a license to establish a pharmacy**
 - ▶ **regardless** if it is a holder of a license to practice pharmacy or not
 - ▶ exemption: license can be granted to a legal entity (pharm. cooperatives)
- II) Right to **operate a pharmacy through a company (of special aim)**:
Collective or Limited Partnership (OE/EE), Limited Liability Company (EPE) or
Private Capital Company (IKE)
- III) Right to partners and licensees to **participate in up to 10 pharmacies**
- IV) Right to **operate only one store or branch per license**



AGGELOU LAW FIRM
ATTORNEYS & COUNSELORS AT LAW

...And prohibits absolutely

I) The establishment of a Public Limited Company (Societe Anonyme, AE)

II) The shareholding in a pharmacy company, of any individual or company, who:

- ▶ **practices medicine in any specialization/has any interest in diagnostic laboratory**
or
- ▶ **is a Marketing Authorization Holder (KAK), Manufacturer, Importer, Agent or Wholesaler**
or
- ▶ **participates in any capacity to any of the above** entities

AND

- ▶ falls **within the 10 larger shareholders or lawful holders of voting rights**
or
- ▶ has the **right to appoint or revoke or represent members of the Board** of the above entities

III) **Same restrictions on family members up to 2nd degree** (doctors' family not included)

ADMINISTRATIVE PENALTY: the withdrawal of license to establish a pharmacy



AGGELOU LAW FIRM
ATTORNEYS & COUNSELORS AT LAW

Finally, how can entrepreneurs co-run a pharmacy?

► THE MYTH:

"They may only participate as licensees-shareholders to Limited Liability Companies where the responsible pharmacist owns at least 20% of company shares."

(33,3% under negotiation)

► THE WHOLE TRUTH:

"They may also participate with a percentage up to 99% to any kind of permitted company, provided that the license to establish belongs to the pharmacist."

(abolishment of art. 6 of Law 328/76 by means of art. 2 N. 4336/2015)



Liberalization of prices in OTCs

(L. 4254/2014, L. 4472/17)

I) Legal obligation: mandatory since **1.1.2017**/excluded OTCs for use in hospital

prices fixed till **7/2017**

II) OTCs:

- currently fully liberalized for wholesalers and retailers
- strong upward adjustment-tendency to alignment

III) The invention of “**Indicative Retail Price**”

- **reference obligatory**
- **non binding**

IV) **Sticking point** between pharmacists and consumers



AGGELOU LAW FIRM
ATTORNEYS & COUNSELORS AT LAW

Liberalization of points of sale IN OTCs

(L. 4389/2016)

✓ “OTCs OUT OF PHARMACY”: **CASUS BELLI !!!**

Subcategory of OTCs: General Distribution Medicines (**GE.DI.FA**)-216 APIs

Criterion for classification: proven low risk for consumers/ **remarkably low interest**

I) GE.DI.FA.: **exclusively** through:

- a. Pharmacies
- b. Super Markets (**forbidden** through related e-shops)
- c. Groceries (**forbidden** through related e-shop)



II) As **an exemption to the rule** through certified e-pharmacies complying with the EU common logo [Min.Dec. 51194/18.7.2016]

III) **Without the presence of pharmacist or assistant**

IV) **Wholesale distribution** by retailers is **prohibited**



AGGELOU LAW FIRM
ATTORNEYS & COUNSELORS AT LAW

Impact of De-regulation: comparative view

- Decreasing pharmaceutical expenditure/ prices of OTCs: ✗
- Unequal territorial distribution of pharmacies: ✓
- Stocks according to profitability /controlled by Groups: ✓
- Creation of Monopolies-Chains: ✓
- Slight deterioration of the quality (reduction of time for the best possible advice): ✓
- Distortion of the scientific profile of the pharmacy: ✓
- Tax Evasion Phenomena (the Boots case, 2013): ✓
 - Timid attempts to **re-regulate ownership**



Let history prove it right or wrong...



AGGELOU LAW FIRM
ATTORNEYS & COUNSELORS AT LAW

**THANK YOU
FOR YOUR
ATTENTION**

Sofia Aggelou

Tel: +30 210 3645915

E-mail:

s.aggelou@aggeloulawfirm.gr



AGGELOU LAW FIRM
ATTORNEYS & COUNSELORS AT LAW