WORLD TRADE ORGANIZATION

G/LIC/N/3/ALB/4
23 October 2009

(09-5254)

Committee on Import Licensing Original: English

REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES[1]

Notification under Article 7.3 of the Agreement on Import Licensing Procedures for 2008

ALBANIA

The following communication, dated 19 October 2009, is being circulated at the request of the delegation of Albania.

Albania's import licensing regime, as notified in document G/LIC/N/3/ALB/3 has not been modified and still remains valid for 2009, except for the change introduced in the Questionnaire on import licensing procedures for medical products attached hereto[2].

[1] See G/LIC/3, Annex, for the Questionnaire.
[2] In English only.

LAW No. 10 008 Dated 27.10.2008

RELATED TO SOME ADDENDA AND AMENDMENTS TO LAW NO. 9223, DATED 25.11.2004 "FOR MEDICAMENTS AND PHARMACEUTICAL SERVICE", AMENDED

Pursuant to articles 78 and 83, item 1 of Constitution, upon the proposal of Council of Ministers,

**ASSEMBLY
OF REPUBLIC OF ALBANIA
DECIDED:**

To add the following addenda and amendments to law no. 9223 dated 25.11.2004 "For medicaments and pharmaceutical service", amended.

Article 1

Items 28 and 29, with the following content, shall be added to article 3 titled "Definitions":

28. 'Regional Public Health Directorate' (hereinafter Regional PHD) shall remain the authority which coordinates, governs, and supervises all health service on national level through pharmaceutical structures comprised of pharmacists.

29. 'Pharmacist' shall mean a professional who has been conferred a degree as pharmacist after a unique 5-year period of studies (Second Level Integrated Degree). All the degrees awarded by University of Tirana, pharmacy branch, pursuant to former program as approved by Ministry of Health and Science and foreign degrees in pharmacy, recognized by such ministry, and shall be bear equal recognition.

Article 2

Article 17 shall be amended as follows:

'Article 17
Accelerated registration procedures

Medicaments registered under European Medicaments Evaluation Agency (EMEA), American Administration for Food and Medicaments (FDA), medicaments registered in Switzerland, Canada, and Australia as well as medicaments registered pursuant to communitarian procedures of EU, shall automatically be registered within 30 working days after proving the authenticity of the documentation submitted".

Article 3

Article 18 shall be amended as follows:

"Article 18
Publication of medicaments register

1) National Centre for Medicaments Control (NCMC) shall publish periodically and annually the register containing relevant prices and names of importers authorized by license holding firms or manufacturing ones and updates it on monthly basis.

2) National Centre for Medicaments Control (NCMC) shall be responsible to submit medicaments register and its updates to Customs General Directorate.

3) National Centre for Medicaments Control (NCMC) shall be responsible to notify immediately pharmaceutical bodies and Customs General Directorate with regard to each new medicament registered or disqualified/excluded and for each medicament imported under special authorization".

Article 4

Article 20 shall be amended as follows:

"Article 20
Control stamp

1) All medicaments traded in the market shall necessarily bear the control stamped provided by National Centre for Medicaments Control (NCMC).

2) The control stamp shall be duplicate and at least contain the following elements:
   a) medicaments name and dosage;
   b) retail price;
   c) authorized importer's name.

3) The other elements of control stamp and stamping or manufacturing procedures shall be determined by a decision of Council of Ministers.

Article 5

Article 24 shall be amended as follows:

"Article 24
Medicaments wholesale

1) The activity of medicaments wholesale shall be exercised by legal subjects, domestic or foreigners, equipped by a license provided only by Ministry of Health.

2) To launch the afore-mentioned activity, the interested subject shall declare, upon his/her own responsibility, that he/she meets all the requirements provided for by the existing relevant legislation.

3) Regional Public Health Directorate shall verify the statements submitted by the legal subject within 20 working days.

4) If such an authority fails to provide a reply, the pharmaceutical directorate at Ministry of Health, within 5 working days, shall forward such procedures to National Centre for Medicaments Control, which shall provide an answer with 10 working days.

5) After the receipt of inspection report issued by the relevant Public Health Directorate or National Centre for Medicaments Control, Ministry of Health shall issue the license within 10 working days. The license shall be distributed to legal subject by regional offices of Public Health Directorate.

6) Pharmaceutical distributor shall have contracted as employee a technical manager who is a pharmacist by profession.

7) The technical manager and pharmacists shall be registered to regional Public Health Directorate.

8) The subject licensed for medicament wholesale may trade on wholesale basis even treating materials, accessories such as hygienic, cosmetic or diet related items.

9) Criteria and approval procedures of such activity as well as the type of self-declaration shall be determined by a decision of Council of Ministers".

Article 6

Article 25 shall be amended as follows:

"Article 25
Technical manager of pharmaceutical distributor

Importer, exporter, and pharmaceutical distributor's technical manager shall mean a pharmacist, member of Pharmacist Order of Albania, with a 2-year working experience in pharmaceutical sector, responsible for all the technical and professional activity of the relevant legal subject.

Article 7

Letter "b" of article 31 shall be amended as follows: "b) shall possess a two-year working experience".

Article 8

Article 32 shall be amended as follows:

"Article 32
Pharmacy

1) The activity of pharmacy may be exercised by all physical or legal subjects, domestic or foreigner, licensed by regional Public Health Directorate.

2) To launch the afore-mentioned activity, the interested subject shall declare, upon his/her own responsibility, that he/she meets all the requirements provided for by the existing relevant legislation.

3) A false statement shall result in a five-year license banning.

4) Regional Public Health Directorate shall verify the statements submitted by the legal subject within 20 working days.

5) If such an authority fails to provide a reply within this deadline, the activity shall be regarded as approved.

6) Regional Public Health Directorate shall notify periodically to National Centre for Medicaments Control, within 10 working days, with regard to each new pharmacy established in its territory.

7) National Centre for Medicaments Control shall carry out an inspection of the activity within 5 working days from such a notification.

8) Pharmacy shall be permitted to exercise the activity at the presence of technical manager and employed pharmacist.

9) Technical manager shall be licensed for only a single pharmacy.

10) Technical manager and pharmacists employed at a pharmacy shall be registered to regional Public Health Directorate.

11) Criteria and approval procedures of such activity as well as the type of self-declaration shall be determined by a decision of Council of Ministers".

Article 9

Articles 33 and 34 shall be repealed.

Article 10

Article 35 shall be amended as follows:

"Article 35
Pharmaceutical agency

1) In rural areas, where no pharmacy operates, the establishment of pharmaceutical pharmacies with an assistant pharmacist as a technical manager shall be approved on the basis self declaration to meet the required criteria.

2) To initiate the activity of medicament trading by means of pharmaceutical agency, the procedures provided for by article 32 of the current law shall be followed.

3) Pharmaceutical agency shall exercise retail trading of medicaments as provided for in the list approved by Minister of Health".

Article 11

Article 46 shall be amended as follows:

"Article 46
The activity of medicaments import – export

1) The activity of medicaments import – export shall be exercised by legal subjects, domestic or foreigner, after the receipt of professional license regarding the technical manager as a pharmacist with a two-year professional working experience.

2) To secure such a license, the subject shall follow the procedures provided for by article 24 of the current law".

Article 12

Article 47 shall be amended as follows:

"Article 47
Import of registered medicaments

1) Medicaments registered in the Republic of Albania shall be imported by subjects authorized by license holding firms or manufacturing ones pursuant to medicaments published register as provided for by article 18 of the actual law.

2) Import procedures shall be performed in entry customs offices at the presence of pharmaceutical inspector".

Article 13

Article 58 shall be amended as follows:

"Article 58
Annulment of approved activities, license withdrawal and medicament seizure and confiscation.

1) When pharmaceutical inspectors observe administrative violations pursuant to article 57 of the actual law, they shall submit a proposal to relevant Public Health Directorate and notify Ministry of Health with regard to:

a) suspension of activity;
b) license withdrawal

2) Pharmaceutical inspectors shall seize and confiscate medicaments in cases of violations provided for by the actual law.

Article 14

Article 59 shall be amended as follows:

"Article 59
Administration and elimination/destruction of confiscated medicaments

1) Confiscated medicaments, which happen to be usable and properly documented, shall fall under the administration of Ministry of Health.

2) Seized or confiscated medicaments, which happen to be not usable, shall be destroyed at the presence of pharmaceutical inspectors and properly documented pursuant to the manner provided for by legislation for protection of environment at the expense of the subject which has performed such violation".

Article 15

The actual law shall enter into force 15 days after its publication in the Official Bulletin.

SPEAKER
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