«ԱԿԱԴԵՄԻԿՈՍ ԷՄԻԼ ԳԱԲՐԻԵԼՅԱՆԻ ԱՆՎԱՆ ԴԵՂԵՐԻ ԵՎ ԲԺՇԿԱԿԱՆ ՏԵԽՆՈԼՈԳԻԱՆԵՐԻ ՓՈՐՁԱԳԻՏԱԿԱՆ ԿԵՆՏՐՈՆ» ՓԲԸ
«НАУЧНЫЙ ЦЕНТР ЭКСПЕРТИЗЫ ЛЕКАРСТВ И МЕДИЦИНСКИХ ТЕХНОЛОГИЙ ИМЕНИ АКАДЕМИКА ЭМИЛЯ ГАБРИЕЛЯНА» АОЗТ
«SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN EMIL GABRIELYAN» CJSC

Կոմիտաս պող. 49/4, Երևան 0051, Հայաստան
пр. Комитаса 49/4, Ереван 0051, Армения
49/4 Komitas aven., Yerevan 0051, Armenia

Հեռ. (+374 10) 23-16-82, 23-08-96, 23-47-32, 23-20-91
Tel.: (+374 10) 23-16-82, 23-08-96, 23-47-32, 23-20-91
Fax: (+374 10) 23-29-42, 23-21-18
E-mail: admin@pharm.am ; URL: http://www.pharm.am

0101037816
12.03.16

Dear Sir/Madam,

In order to properly organize the Scientific centre document circulation you are kindly asked to follow below mentioned instructions[1]:

A. About documents to be submitted
1. Submission order
1.1 Cover letters.

All submitting documents, document attachments, documents presented in the registration dossier of medicinal product should correspond to following requirements:

1. A4- size paper format
2. Easily legible (even after photocopying or scanning),
3. Paginated (if multi-page)
4. One-sided printing
5. The left-hand margin should be larger than the right-hand margin (documents should be punched)

All documents submitted to the Scientific centre should be accompanied with a cover letter. Cover letter should be prepared, signed and submitted by Marketing authorization holder or its authorized representative in the Republic of Armenia (RA). Separate cover letters should be presented for each medicinal product (for each pharmaceutical form, dosage strength, for each output form for sterile pharmaceutical forms). Cover letter for the submission of documents (additional, missed or incomplete) at the request of the Scientific centre should mandatorily contain following data:

- Number and date of outgoing letter of the Scientific centre,
- Trade name, pharmaceutical form and strength of the medicinal product, also output form for sterile pharmaceutical forms,
- Name and country of the Marketing authorization holder and/or Manufacturer,
- The names of attached documents.

[1] This letter is an overall and updated version of the Scientific centre's circular letters N 0101149514 dated 22.12.2014, N 0101079410 dated 07.10.2010 and February 2009.

If submitting documents are not required by the Scientific centre, it is **also** necessary to clarify the purpose of submission.

Cover letters regarding post-registration changes should be prepared either by Marketing authorization holder or by Manufacturer and accompanied with comparison table.

In order to avoid excessive delays during the medicinal product expertise the Scientific centre required data need to be submitted **at once**.

The submission of the registration dossiers, samples and standards are implemented exclusively via handling/acceptance acts.

Cover letters containing information on several medicinal products, as well as handwritten letters will be rejected by the Scientific centre.

The templates of covers letters are attached.

1.2 Documents attached to cover letter.

Documents attached to cover letter should **also** correspond to following requirements:

1. If the submitted documents (hard copies) are voluminous, it is necessary to submit in two-whole A4-sized folder, separating documents from each other with dividers. The folder should possibly have a label with data on the trade name, pharmaceutical form and strength, Manufacturer's and/or Marketing authorization holder of the medicinal product. The package of documents should have "Content" with necessarily mentioned order, names and number of pages of the documents.
2. If the attached document is submitted on a CD, then this should be stated in the cover letter (mention the password as well, if available). Electronic documentation (CD) acceptable formats are Microsoft Word, high quality, text-selectable PDF. The CD should be labeled with the trade name, pharmaceutical form and strength, Manufacturer's and/or Marketing authorization holder of the medicinal product, if it is possible.

You may continue sending letters via e-mail addressing to the official e-mail address of the Scientific centre: admin@pharm.am. At the same time:

1. Mention the trade name, pharmaceutical form and strength, Manufacturer's and/or Marketing authorization holder of the medicinal product, if it is possible, as "Subject" of an e-mail,
2. Electronic documentation (CD) acceptable formats are Microsoft Word, high quality, text-selectable PDF,
3. Cover letter as well as the explanatory letters should be submitted as one file and titled "Letter",
4. Documents listed in the cover letter should be attached and not submitted as a link.
5. Depending on documents size they can be sent in parts by mentioning "Part 1", "Part 2" etc. in the "Subject" of e-mail. The cover letter as well as the explanatory letters should be attached to "Part 1".
6. The titles of attached documents should be identical to ones mentioned in the cover letter.

7. The total size of files sent to admin@pharm.am via an e-mail should not exceed 40Mb.
8. E-mails that contain documents intended for several medicinal products will not be accepted by the Scientific centre. In these cases the sender will receive a notification from admin@pharm.am .

Documents, registration dossiers, samples and standards may be sent to the Scientific centre by regular mail or by courier service. Please find the postal details of the Scientific centre below:

Scientific centre of drug and medical technology
expertise after academician Emil Gabrielyan CJSC
Komitas Av. 49/4, Yerevan 0051
Republic of Armenia
Tel: (+374 10) 23-16-82, 23-08-96, 23-47-32, 23-20-91
Fax: (+374 10) 23-29-42, 23-21-18
E-mail: admin@pharm.am
URL: http://www.pharm.am

You will be issued the relevant invoice in case of Custom Clearance that is subject to be payed within 5 banking days. When sending registration dossiers, samples and standards it is necessary to attach handling/acceptance acts which will be returned via e-mail after signing.

You are kindly informed that letters, registration dossiers, samples and standards will be accepted every working day from **10.00 till 13.00** and **from 14.00 till 16.30**.

We appreciate your support in matter of proper organization of letters, registration dossiers, samples and standards distribution as well as electronic documents circulation.

B. About outgoing documents.

1. Issuing procedure.

The information on issuing of the outgoing documents mentioned below is implemented via letters@pharm.am, the e-mail of the Scientific centre:

- Letters,
- Contracts and appropriate appendices on rendering expertise services,
- Registration certificates,
- Acceptance acts on rendering expertise services,
- Invoices on reimbursement of the registration dossiers, samples and standards custom expenses,
- Projects of registration certificates, as well as medicinal product mock-ups, leaflet inserts (instruction for use) and summary of product characteristics subject to approval.

Electronic (scanned) versions of documents mentioned above, except for financial documents and registration certificates are being sent either to Marketing authorization holder or to its authorized representative in the RA. If there is no authorized representative in the RA the

electronic (scanned) versions of financial documents and registration certificates as well are being sent.

In order to properly carry out the procedure the Marketing authorization holders or their authorized representatives in the RA are advised to constantly keep contact details (name and last name, address, phone number, fax, e-mail) as well as authorizations (should have a proper verification) of responsible persons updated. The data change, the relevant information should be sent to admin@pharm.am and letters@pharm.am as soon as possible.

Your remarks or suggestions on outgoing documents, as well as the data required with the outgoing letters should only be sent to the e-mail address admin@pharm.am, except for:

- Projects and signed versions of registration certificates, as well as medicinal product mock-ups, leaflet inserts (instruction for use) and summary of product characteristics subject to approval which should be sent to e-mail address project-reply@pharm.am
- Acceptance acts on rendering expertise services and their signed versions that should be sent to the e-mail address armine@pharm.am.

We would also like to inform you that outgoing documents as well as originals of documents submitted via e-mail will be handed over to you every working day **from 10.00 till 13.00** and **from 14.00 till 16.30.**

Letters or Expert conclusions on rendering chargeable services by the Scientific centre will be handed over after submission of payment confirming document.

The companies, that do not have authorized representative in the RA, may order a courier service for the receipt of original documents.

Template 1

To: Hakob Topchyan, Director of the Scientific centre
of drug and medical technology expertise after academician Emil Gabrielyan,
From: ----------
(Marketing authorization holder name or its authorized representative's name and last name in the RA)

Dear Mr. Topchyan,

In response to your letter N---------- dated --------- please find attached required documents mentioned below for medicinal product ---------- manufactured by ----------:

1. ..... (indicate name of the document),
2. ..... (indicate name of the document) and so…

Template 2

To: Hakob Topchyan, Director of the Scientific centre
of drug and medical technology expertise after academician Emil Gabrielyan,
From: ----------
(Marketing authorization holder name or its authorized representative's name and last name in the RA)

Dear Mr. Topchyan,

Please be informed that there has been carried out a post-registration change of the medicinal product _____ manufactured by _____, registered in the RA (change should be described).

In case of necessity to make a re-formulation of the registration certificate the required payments of State Tax and Expertise Fee are guaranteed.

The following documents of the medicinal product are attached:

1. ..... (indicate name of the document),
2. ..... (indicate name of the document) and so…