**ANNEX 2 OF RESOLUTION No. 333-2013 (COMIECO-LXVI)**

**MUTUAL RECOGNITION OF HEALTH REGISTRATION FOR PHARMACEUTICALS FOR HUMAN USE**

**SCOPE OF APPLICATION**

The Recognition applies to the health registration of pharmaceuticals originating in the countries.

1. **REQUIREMENTS**
2. Proof of payment.
3. Application for recognition of registration signed and sealed by the responsible person and the Licensee or his legal representative, to the Regulatory Authorities of the countries.
4. Power of attorney duly legalised attesting to the legal or technical representation given by the owner to the natural or legal person residing permanently in the country where the mutual recognition is sought. If the legal representative possesses the authority he may grant the power to the responsible person.
5. Original Certificate of Pharmaceutical Product issued by the country of origin, duly legalised, including the qualitative and quantitative formula, the useful lifetime, the approved storage conditions, the approved selling method of the product and the compliance with Good Practices Manufacturing of the laboratory of the manufacturer. When two or more laboratories are involved in the manufacturing process, the identification of the companies and the compliance with Good Manufacturing Practices should be included as an annex.
6. The person concerned shall submit a copy of the complete dossier along with an affidavit stating that it is a true copy of the one presented in the country where registration was performed, in order to obtain the information necessary to perform the health surveillance after recognition. This requirement will be presented at the time of delivery of the document of approval of recognition.
7. **PROCEDURE**
8. Presentation of the requirements established to the regulatory authority.
9. The Regulatory Authority verifies the requirements presented.
10. The Regulatory Authority decides within a period of 8 working days, issuing the respective document in accordance with Annex II.
11. In the case of approval the RM code and initial of the country that performs recognition and that precedes the serial number given by the country will be assigned, which will be retained at the time of renewal. This code must be included in the manner that is established for the health registration number in the current RTCA on Labelling of Pharmaceuticals. The validity period will be the same as the original registration.
12. **RECOGNITION OF CHANGES IN REGISTRATION**
    1. **REQUIREMENTS**
13. Application for recognition of the amendment to the registration signed and sealed by the person responsible and Licensee or his legal representative, to the Regulatory Authorities of the countries.
14. A copy of the documentation supporting the change in accordance with Annex 1 of the “RTCA Pharmaceuticals. Pharmaceutical Products for Human Use. Health Registration requirements”, in order to obtain the information necessary to perform health surveillance. This requirement will be presented at the time of delivery of the document of approval of recognition.
15. Document of approval of the change.
    1. **PROCEDURE**
16. Presentation of the requirements established to the regulatory authority.
17. The Regulatory Authority verifies the requirements presented.
18. The Regulatory Authority decides within a period of 8 working days, issuing the respective document in accordance with Annex II.
19. In case of approval the applicant delivers supporting documentation, at the time of receiving the document.
20. **RENEWAL OF RECOGNITION OF THE REGISTRATION**
    1. **REQUIREMENTS**
21. Proof of payment.
22. Application for recognition of the renewal to the registration signed and sealed by the person responsible and Licensee or his legal representative, to the Regulatory Authorities of the countries.
23. Original Certificate of Pharmaceutical Product issued by the country of origin, duly legalised, including the qualitative and quantitative formula, the useful lifetime, the approved storage conditions, the approved selling method of the product and the compliance with Good Practices Manufacturing of the laboratory of the manufacturer. When two or more laboratories are involved in the manufacturing process, the identification of the companies and the compliance with Good Manufacturing Practices should be included as an annex.
    * 1. If at the time of the renewal of the recognition there are modifications or changes to the original record that have not notified one must submit:
24. Application for renewal of recognition that includes the post-registration changes that are not notified.
25. Document of approval of the change.
26. A copy of the documentation supporting the change in accordance with Annex 1 of the “RTCA Pharmaceuticals. Pharmaceutical Products for Human Use. Health Registration requirements”, in order to obtain the information necessary to perform health surveillance. This requirement will be presented at the time of delivery of the document of approval of recognition.
    1. PROCEDURE
27. Presentation of the requirements established to the regulatory authority.
28. The Regulatory Authority verifies the requirements presented.
29. The Regulatory Authority decides within a period of 8 working days, issuing the respective document in accordance with Annex II.
30. In case of approval the number of recognition and enforcement granted in the renewal of the registration must be kept.
31. The applicant delivers the documentation that supports the change, at the time of the approval of the renewal.
32. **REASONS FOR NON-RECOGNITION**

Recognition of registration is not granted when:

1. Confusion or sameness exists in the trade name of a previously registered pharmaceutical product.
2. The medicine contains active ingredients or combinations thereof, which have no documented scientific evidence of safety and efficacy.
3. A formulation combining active ingredients of chemical synthesis with natural medicinal products, and this combination is not catalogued as medication.
4. The formulation is a nutritional supplement or natural medicinal products.
5. There is an international alert that questions the safety and efficacy of the active ingredient or combinations thereof.
6. In case of co-packaging in which there is no scientific justification for the scheme of requested treatment.
7. If the selling method approved in the registration of the country of origin differs from the country of recognition.
8. **REASONS FOR CANCELLATION**
9. The product proves to be harmful or non-safe under normal conditions of use.
10. It has been proven by conclusive scientific evidence that the product is not therapeutically effective.
11. When it is proven that the product has no authorised quantitative or qualitative composition or when guarantees of quality and stability are breached, as declared in the file.
12. Where deceitfulness is shown in the data and information contained in the dossier submitted for Mutual Recognition.
13. Where prior warning, the labelling with which the product is marketed in the country of recognition is different from the approved labelling in the original registration.
14. That for any other valid reason constitutes a foreseeable risk to the health or safety of people.
15. When the regulatory authority that granted the original registration notify the cancellation of the same.
16. Upon request for recognition by the registration holder.
17. **RECOGNITION OF CO-PACKAGED GOODS**

In the event that an application for recognition for co-packaged pharmaceuticals is made one must submit:

1. Proof of payment.
2. Application for recognition of the co-packaged goods signed and sealed by the responsible professional and Licensee or his legal representative, to the Regulatory Authorities of the countries.
3. Certificate of pharmaceutical product that includes, for each of the co-packaged products the qualitative and quantitative formula, the useful lifetime, the approved storage conditions, the approved selling method of the product and the compliance with Good Practices Manufacturing of the laboratory of the manufacturer. When two or more laboratories are involved in the manufacturing process, the identification of the companies and the compliance with Good Manufacturing Practices should be included as an annex.
4. Document of approval of the co-packaged goods issued by the Regulatory Authority in the country of original registration.
5. The person concerned shall submit a copy of the complete dossier along with an affidavit stating that the document presented is a true copy of the one presented in the country where registration was performed, in order to obtain the information necessary to perform the health surveillance after recognition. This requirement will be presented at the time of delivery of the document of approval of recognition.
6. A copy of the draft or original package, approved.
7. **GENERAL PROVISIONS**
8. For Costa Rica the Mutual Recognition Procedure applies to medications that have been registered with the current harmonised rules.
9. For products of the CA-4[[1]](#footnote-1) that the date of entry into force of this procedure have been recognised as medications and are classified as a nutritional supplement or natural product will not be renewed.
10. One cannot market a product without having notified the modifications made to the original registration.
11. For products subject to protection of test data, the current regulations of each country shall apply.
12. Products that require bioequivalence studies are subject to the current regulations of each country.
13. This procedure does not apply to biological and biotechnological products.

**ANNEX I**

**(NORMATIVE)**

**INFORMATION TO INCLUDE IN THE APPLICATION FOR RECOGNITION**

1. Type of procedure
   1. Recognition
   2. Renewal
   3. Modification/Amendment
   4. Co-packaged goods
2. Product details
   1. Product name
   2. The name of the active principles with its international non-proprietary name.
   3. Pharmaceutical form.
   4. Route of administration.
   5. Presentation of the product.
   6. Approved shelf life and storage conditions.
   7. Therapeutic group.
   8. Selling method.
3. Manufacturer and packager details:
   1. Name of the laboratory or laboratories involved in the manufacture and packaging of the product.
   2. Address, telephone, fax and email.
   3. Stage of manufacturing process.
   4. Country of the laboratory or laboratories participating in the manufacture and packaging of the product.
4. Details of the owner of the product:
   1. Name.
   2. Address, telephone, fax and email.
   3. Country.
5. Details of the distributor(s):
   1. Name of the distributor(s).
   2. Address, telephone, fax and email.
   3. Health license number and expiration date.
6. Details of the legal representative:
   1. Name.
   2. ID number.
   3. Address, telephone, fax and email.
7. Details of physical/natural or legal person registering:
   1. Name.
   2. ID number.
   3. Address, telephone, fax and email.
8. Details of the responsible professional:
   1. Name.
   2. ID number.
   3. Address, telephone, fax and email.
   4. Member number or chemical pharmaceutical enrolment.

**ANNEX II**

**INFORMATION TO BE INCLUDED IN THE DOCUMENT OF APPROVAL ISSUED BY THE REGULATORY AUTHORITY OF STATES PARTIES TO REQUEST FOR RECOGNITION**

IDENTIFICATION OF THE REGULATORY AUTHORITY THAT APPROVES OR REJECTS THE RECOGNITION

Based on the provisions of Resolution COMIECO No. **333-13** recognizes the (*Health Registration, Registration Renewal, Amendments to the Health Registration, Co-packaged Goods*) drug granted by the Regulatory Authority:

Product: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Generic name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Route of administration: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Pharmaceutical form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Concentration per unit dosage: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Presentation of the product: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approved shelf life: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Storage conditions: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the registration holder: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Method of sales: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Health registration identification number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Period of validity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Regulatory Authority Signature and stamp: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**-END OF DOCUMENT-**

1. Central American 4, i.e. El Salvador, Guatemala, Honduras and Guatemala. [↑](#footnote-ref-1)