**RESOLUTION No. RE- SERCOP-2016-0000072**

**[…]**

## CHAPTER II
## DRUG PROCUREMENT THROUGH DRUGS E-INVENTORY

### Section I
### Mandatory Use of Drugs e-Inventory

**Art. 379. Mandatory purchase through e-Inventory.-** All entities enclosed in the article 1 of the Organic Law of the National Procurement System that need to purchase drugs that are listed in the e-Inventory that is managed by the National Public Procurement Service, must perform such purchase using mandatorily the e-Inventory.

### Section II
### Provisions to Rule the Procedure of the Corporate Reverse Drugs Bidding

**Art 380.- Drug procurement through the Drugs e-Inventory-** This Section intends to regulate the procedure of the Corporate Reverse Drugs Bidding that will be executed by the National Public Procurement Service and the members of the Public Integral Health Network –RPIS by the acronym in Spanish- which encompasses the Public Health Ministry –MSP by the acronym in Spanish- Army Social Security Institute –ISSFA by the acronym in Spanish-, National Police Social Security Institute –ISSPOL by the acronym in Spanish- and National Social Security Institute –IESS by the acronym in Spanish-; for the procurement of drugs for human use and consumption, published by the Website of the National Public Procurement Service under the tool Drugs e-Inventory, www.sercop.gob.ec.

**Art. 381.- Information Update of Registry of Suppliers -RUP.-** Bidders interested to participate in the Corporate Reverse Drugs Bidding should update their information in the Registry of Suppliers, which will be used for the submission of the offer. This update can be done until 48 hours before the end of the stage of offer submission (electronic form of adhesion).

The foreign natural or legal persons that haven registered previously should do so online through the institutional Website of National Public Procurement Service until forty eight (48) hours before the end of the stage of offer submission (electronic form of adhesion).

**Art 382.- Verification for suppliers**.- The National Public Procurement Service in any stage of the Corporate Reverse Drugs Bidding SICM, shall verify the documentation and information submitted by the suppliers at registration in the Registry of Suppliers. Should the National Public Procurement Service identify that the information or documentation entered through the institutional Website of SERCOP is false or misleading shall apply to that supplier the penalties provided in the law.

**Art. 383.- Responsibilities.-** The different areas of the National Public Procurement Service, the Members of the Public Integral Health Network or its delegates will have the following responsibilities:

1. The General Directorate of Planning and Strategic Management, General Directorate of Legal Advisory, the Technical Operations Directorate, the Technical Directorate of Technological Innovation, Technical Directorate of Controversies, the Project Leader, with the support of the needed Department dependent of each one of the aforementioned Directorates, and in articulation with the members of the Public Integral Health Network or its delegates shall be responsible for performing the process of Corporate Reverse Drugs Bidding, in each one of the stages: preparation, pre-contractual and awarding stage.

2. The General Deputy Director, the Procurement Research Department, Risk Department and the Department of Electronic Catalog, shall articulate and determine, in relation to the information provided by the agencies that are part of the Public Integral Health Network - RPIS, the reference budget that will be used in the Corporate Reverse Drugs Bidding, taking as parameters, among others, historical drug procurement prices by the RPIS, those set by the National Council of Setting and Reviewing Prices of Drugs of human use and consumption, evidence of international prices and other parameters that may be appropriate prior authorization of the General Director of National Public Procurement Service;

3. The Deputy Director of Control, in conjunction with the General Directorate of Legal Advisory, shall write the tender specification, same that shall be informed to the

entities that are part of the RPIS and shall be given to the General Director of National Public Procurement Service for approval;

4. The Technical Directorate of Technological Innovation and its Departments, shall publish on the Website of the National Public Procurement Service, the date, time and user that is responsible for the publication of documents, on the links "results and files" and all information related to the processes in order to establish automatically the people responsible of it; as well as the actual date and time of the different states of the supplier and not at the query date.

5. The General Assistant Director, with the assistance and collaboration of the Departments of Research, Risk and Electronic Catalog, in the case that the processes of SICM would require better and reduced prices than the ones set in the processes being executed, ought to report this fact immediately to the General Director of National Public Procurement Service, in order to take adequate decisions to avoid economic harm to the Government, and in case of suspension for new price setting and until the adjustment would result beneficial of the public interest will report to the Technical Directorate of Technological Innovation to temporarily disable the drug name from the Drugs e-Inventory;

6. The Directorate of Planning and Strategic Management in conjunction with the Project Leader will inform, immediately in writing, the General Director of the National Public Procurement Service regarding planning, follow-up actions, periodic evaluations of the process, implemented in order to achieve SICM goals and objectives, and to implement the decisions taken by the Technical Commission about the Corporate Reverse Drugs Bidding.

7. The Legal Advisory Department of the National Public Procurement Service shall advice the Technical Commission in all legal issues during the implementation of the procedure of the Corporate Reverse Drugs Bidding; and by request of it shall issue legal reports.

8. Where there were different criteria among the members of the Technical Commission, for enabling or disabling one or more bids, the Legal Advisory Department shall issue a no binding legal ruling, which shall be presented to the Technical Commission, which shall be attached in the report recommendation for awarding or declaration of process void due to no-show to prove legality, fair and equal treatment to tenders.

9. The Technology Directorate for Technological Innovation shall implement the policy of monitoring, validation and verification of the implementation of the computer system that supports the Public Procurement Website, action which will generate reports on the system functionality, so that the General Director of the National Public Procurement Service takes appropriate decisions.

10. RPIS members, shall analyze the prices of medicines awarded in the Corporate Reverse Drugs Bidding and will compare them against prices of their purchases on national level in order to establish the existence of offers at lower prices and will inform the General Director of the National Public Procurement Service, to take the necessary measures to extend these costs, by the execution of General Agreements to the other Contracting Entities.

11. RPIS members will officially inform the General Director of the National Public Procurement Service about the consolidated list of drugs and the referential quantities for a period of 24 months, object of the Corporate Reverse Drugs Bidding. The National Health Authority should forward the technical sheet for each drug.

12. RPIS members will officially inform the General Director of the National Public Procurement Service about the distribution of drugs, object of the Corporate Reverse Drugs Bidding, for each health unit that is part of the RPIS.

13. RPIS members will inform the General Director of the National Public Procurement Service about the drug-therapeutic criteria and other technical conditions which must be incorporated in the tender specifications of Corporate Reverse Drugs Bidding.

The National Agency for Regulation, Control and Health Surveillance (ARCSA) acronymin Spanish) will inform the General Director of the National Public Procurement Service bout the pharmacovigilance mechanisms and post control.

**Art. 384.- Technical Commission.-** To carry out the process of Corporate Reverse Drugs Bidding a Technical Commission shall be created, in compliance with Article 78 of the General Regulation of the Organic Law of the National Public Procurement Service. The Coordinator of the National Public Procurement Service Law Advisory or his delegate will act as secretary.

The Technical Commission is responsible for:

1. Meet periodically during each step of the Corporate Reverse Drugs Bidding, with at least three of its members, as under Article 80 of the General Regulations of the Organic Law of the National Public Procurement System. The President will have casting vote.

2. Respond in a timely manner, within the stipulated term stated in the schedule of tender specifications, the questions and clarifications about the tender specifications and Technical Sheets that are submitted by suppliers. Questions and answers from the suppliers can motivate the modification of the Technical Sheets, as long as they don't require a change in the object of the General Agreement nor in the referential budget per unit.

3. Will give the General Director of the National Public Procurement Service, or his/her delegate a report about the reasons that drive recommendations to suspend a procedure in the Corporate Reverse Drugs Bidding that is in the condition *to be awarded*, so that the General Director of the National Public Procurement Service or his/her delegate can decide.

4. Issue a report to the General Director of the National Public Procurement Service, or his/her delegate, about the list of drugs that hadn't been awarded, so that due actions are taken according to the Organic Law of the National Public Procurement System, its Regulations and Resolutions for the objective set by the National Public Procurement Service;

5. Evaluate that suppliers have entered their offer through the electronic form of adherence to the terms and conditions of Tender Specifications; Prior issuing the Report of Recommendation to Award the Contract or to declare it void due to no-show, according to the case, will request the Registration and Customer Service Department a report about the situation of the bidders that are winners of the bid or the negotiation;

6. To issue minutes of each step of the procedure;

7. If required, request the General Coordination of Legal Advisory of the National Public Procurement Service legal advice during the Corporate Reverse Drugs Bidding, and;

8. Others prescribed by the norm or tender specifications.

**Art. 385.- Publication of Tender Specifications and Invitation.-** The National Public Procurement Service shall post the invitation and Tender Specifications in Spanish and English, being the official version the Spanish one, through the institutional Website of the National Public Procurement Service.

All the information that the Technical Commission deems relevant for a correct process of the Corporate Reverse Drugs Bidding and that might encourage more participants, shall be published as an attachment, to the invitation and the tender specifications.

**Art. 386.- Questions, answers, clarifications or modifications.-** The suppliers, through the institutional Website of the National Public Procurement Service, will be able to ask question, requests or clarifications, in Spanish or English, being Spanish the official version, about tender specifications or technical sheets of the procurement processes of the Corporate Reverse Drugs Bidding. The Technical Commission will answer questions in Spanish and make any clarifications or amendments it considers relevant to the tender specifications or technical sheets, on its own initiative or in response to questions from the participants, through the institutional Website of the National Public Procurement Service as long as these modifications do not alter the object of the contract nor the referential budget per unit.

Participants may submit queries within the period established in the schedule of the procedure. The Technical Commission will have a term of maximum five (5) days, starting from the date the questioning phase finished, to answer and clarify or do appropriate corrections.

**Art. 387.- Offer.-** Through the institutional Website of the National Public Procurement Service, until the day an hour set in the schedule of the procedure, suppliers shall submit their adherence offer, accepting digitally and online the terms and conditions of adherence,

specifications contained in the technical sheet of the medicines, commercial, economic and legal conditions laid down in the tender specifications through the electronic form of adhesion

For this purpose, the supplier must give a click on the "Terms and Conditions of Adherence" button.

The presentation of the offer through the electronic form in the institutional Website of the National Public Procurement Service is the presumption of fact, that may be rebutted, that the suppliers complies with the technical, commercial and legal conditions laid down in the tender specifications. Thus, in case such supplier ends up winning the bid or negotiation, as deemed appropriate, it shall submit the documents mentioned in its offer which are required in the tender specifications through the institutional website of the National Public Procurement Service, so that the Technical Commission, before issuing the contract award recommendation report or the report of failed bid to the senior authority, checks that such documentation complies with the requirements of tender specifications.

In accordance with the "Responsibility and Commitment Agreement for the Use of the Official System for National Procurement-SOCE-", the supplier shall assume full responsibility for the information or documentation submitted with the offer through the electronic form and the use of the tools of the Institutional Website of the National Public Procurement Service by means of the access passwords (user name and password)

The digital and online acceptance and adherence itself constitutes acceptance of the bidders' compliance with the technical, commercial and legal conditions required in the tender specifications, so it is implicit that the supplier understands the terms under which he/she shall participate in the contract procedure, that he/she has all the documentation required in the tender specifications, and the means to fulfill his/her offer.

The costs incurred by the bidder for the preparation and submission of the bid, as well as for submission of the necessary documentation from the beginning of the procedure until the execution of the General Agreement shall be the sole responsibility and risk of the bidder, so neither the National Public Procurement Service nor the institutions that are part of the Public Integral Health Network shall recognize any money, nor reimbursement of any kind on this regard.

In the case of foreign suppliers, for the Registry of Suppliers –RUP (Acronym in Spanish)-, previous the submission of the offer through the electronic form of Adhesion, they must have domicile, permanent establishment or a proxy domiciled in Ecuador.

**Art. 388.- Evaluation.-** The Technical Commission shall have, by means of the Official System for National Procurement –SOCE (Acronym in Spanish)-, a report of the enabled bidders to evaluate the submission and acceptance of the electronic form of adhesion through the institutional Website of the National Public Procurement Service, which shall let them enter their initial economic offer.

**Art. 389-. Initial Economic Offer.-** Bidders prior engaging in the bid or negotiation session, as appropriate, shall send their initial economic offer through the institutional Website of the National Public Procurement Service within the time period provided by respective tender specifications.

Such initial economic offer shall be less, in at least one percent (1%), than the referential budget per unit and comply with provisions of article 163 or the Organic Health Law or norms in force.

**Art. 390.- Bid.-** According to the schedule established in the Tender Specifications, if there is more than one bidder, they shall bid to lower the price, which must always be less than their initial economic offer.

The date stated for the reverse bid, according to the schedule set out in the tender specifications, shall not exceed the term of three (3) days from the date on which term expired for the presentation of the initial economic offer.

**Art. 391.- Conditions for the bid.-** On the day and hour established in the tender specifications the bid shall take place to lower the price, for a period of thirty (15) minutes. In this time suppliers will submit their bids trending downwards with respect to the initial economic offer, respecting the minimum variation range for the bid price set out in the tender specifications.

The initial economic offers submitted through the institutional Website of the National Public Procurement Service require bidders to participate in the bidding phase. For the bid to take place there must be at least two bidders who submitted the initial economic offer and submit their economic downward positions (bids) on the scheduled date and time. If there is not the minimum number of bidders participating in the bid, the institutional

Website of the National Public Procurement Service shall automatically reschedule the reverse bid, only once, within the next 24 hours. In such automatic rescheduling it shall be considered as winner the bidder that submits the lowest bid, which might be by bidding or the initial economic offer. Notwithstanding the aforementioned, the Technical Comission of the Corporate Reverse Drugs Bidding may recommend the declaration of void process due to no show to the General Director of SERCOP, or the latter may declare void due to no show based on what is established in article 33 of the Organic Law of the National Public Procurement System.

In the event that the sanction indicated in the previous paragraph is applied, the next best bid will be considered as the winning bidder.

In cases where there are at least two bidders for the bidding phase, and in spite of the rescheduling, the bidders don`t bid, the contracting entity shall declare the procedure as void and should initiate a new one.

The Official System for National Procurement -SOCE, will select the economic offer of lower price from among the bidders who participated with their economic positions.

Note: article edited through articles 9 and 10 of the External Resolution number RE- SERCOP-000073 from December 23rd 2016

**Art. 392.- Preference Margins.-** As stated in article 25.1 of the Organic Law of the National Public Procurement System, the tender specifications for the procedures of the Corporate Reverse Drugs Bidding shall incorporate the preference margins for the bidders of drugs that are considered manufactured in Ecuador, which shall be set according to the provision of the tender specifications.

**Art. 393.- Negotiation.-** For the Corporate Reverse Drugs Bidding there shall be negotiations in the following cases:

a) When there is a single bidder that has submitted its initial economic offer. In the negotiation the supplier must decrease the price al leas 5% from the value of the referential price per unit.

From the negotiation it should be produced written evidence executed by the parts which must be posted in the National Public Procurement Service Website.

Once performed a successful negotiation meeting, and published the result in the institutional Website of the National Public Procurement Service, the Technical Commission shall proceed to verify the qualifying documentation in order to award the procedure.

That the negotiation has been achieved doesn't mean that the contract is awarded.

**Art. 394.- Presentation and verification of documentation.-** The winner supplier of the bid or bidder after a successful negotiation, as applicable, shall within a maximum period of up to sixty (60) days submit the documentation and information, through the institutional website of the National Public Procurement Service, that has been specifically requested in the tender specifications as prerequisite to be awarded. The highest authority of the National Public Procurement Service or his representative may modify this term in a motivated form. This term will be the estimated award date.

In the event that the Technical Commission, verifies that the documentation submitted by the bidder does not meet the requirements of the tender specifications, it will disqualify the supplier and notify the highest authority of the National Public Procurement Service or his representative to initiate the procedure laid down in Article 108 of the Organic Lay of National Public Procurement System for the offense stated under paragraph d) of Article 106 of the aforesaid Act. Notwithstanding the foregoing, the Technical Commission will call the second best bidder in the ranking immediately (72 hours) that meets all requirements of tender specifications, including the obligation to maintain the offer until the signing of the General Agreement. If this bidder called as second choice does not comply with the requirements set forth in the tender specifications in the stipulated term (72 hours), the highest authority of the National Public Procurement Service or his / her delegate shall declare the selection procedure void due to no show, with no limitation of the administrative penalties applicable.

**Art. 395.- Award and execution of the General Agreement.-** Once completed the stage of submission of documentation by the winner bidder, and the recommendation report of the Technical Commission has been issued, to award the contest, to the highest authority of the National Public Procurement Service or his / her delegate, where it will be noted that the bidder meets the requirements of the tender specifications, the highest authority of the National Public Procurement Service or his / her delegate shall award the procurement process and proceed with the execution of the General Agreement in the term of no more

than fifteen (15) days from the date of notification, which is done through the institutional Website of the National Public Procurement Service.

The report of results will be submitted for review and approval of the General Director of the National Public Procurement Service or his delegate, and shall contain:

1. Fulfillment of the requirements of tender specifications and technical sheets.
2. Report of the awarded unit price, obtained through the Official System for National Procurement –SOCE acronym in Spanish. In case of negotiation, the negotiation minute should be exhibited.

**Art. 396.- Penalties for false information.-** If the Technical Commission or the highest authority of the National Public Procurement Service or his / her delegate ascertain that the winning bidder has submitted in its offer false or misleading information, will issued a report with which the General Director of the National Public Procurement Service shall declare it as failed awarded bidder, ordering his information to be added in the register of defaults and proceed to award the next bidder in the ranking as long as it has the required documentation immediately (72 hours) with all requirements set out in tender specifications, in the way stated in these Instructions.

In the absence of more bidders, it will proceed to declare the reverse bidding as void due to no-show.

**Art. 397.- (Repealed)**

Note: article repealed through article 11 of the External Resolution number RE-SERCOP- 2016-000074 from December 23rd 2016.

## Section III

## GENERAL AGREEMENT PERFORMANCE AND PURCHASE ORDERS THROUGH THE DRUGS E-INVENTORY

**Art. 398.- Procedure.-** To purchase drugs through the Drugs e-Inventory, requesting health care providers must:

1. Develop a motivated resolution, signed by the highest authority or his delegate, to purchase the required medicines.

2. Have due budget line certification.
3. Access the institutional Website of the National Public Procurement Service with their RUC, username and password.
4. Access the Electronic Catalogue - Drug e-Inventory.
5. Select the sub-category of medicine. The common international denomination as well as the commercial name of the drug and an icon of description will be displayed, when clicking on one of these two options one can access the supplier's information, price of the drug, General Agreement, attributes (technical sheets) of the drug.
6. Once the drug is selected the contracting entity shall add in the system all required items.
7. A screen with the field of the name of the drug will be displayed, the supplier to whom the purchase order will be generated, the amount required and the budget allotment, which should be filled out by the contracting entity. After completion of these data, the entity may generate the purchase order for the selected item or continue shopping, increasing the items to be purchased;
8. Each change made in the purchase order, should be updated in the system;
9. When the purchase order is generated, the system displays an information confirmation screen in which the data such as RUC, username and password shall be completed. The entity must press "OK" to continue with the process;
10. On the next screen the following fields will need to be filled: time for reception of the medicine, person responsible for receiving it and the number of resolution for the purchase;
11. Contracting entities are advised to confirm details of the purchase.
12. Press "create purchase order".
13. Contracting entities may group several medications or items in a single purchase order, avoiding the generation of several separate item purchase orders.
14. The contracting entities are recommended to shop with a frequency of not less than once a month and not more than every three months.
15. In its first order, the contracting entity may not exceed 13% of its reference quantity for the duration of the General Agreement.
16. In the event that contracting entities request quantities exceeding their reference volume, the delivery period must be extended by the contracting entity without penalties for delay. For this purpose, the contracting entity and the supplier will enter into an agreement to extend the delivery period of the purchase order within

7 days of the purchase order. The National Public Procurement Service will publish in the institutional Website of the SERCOP a model of complementary agreement.

17. Register in the Institutional Website of the National Public Procurement Service partial and total deliveries of the purchase orders generated through the Drug e- Inventory, within a maximum period of 48 hours from the subscription of the partial receipt or total delivery act as appropriate.

18. Generate immediately the payment order of the partial and total deliveries received to the satisfaction of the contracting entity.

19. Deliver to the governing entity of public procurement, the information that it requires in the formats and times requested. In case of evidence of non- compliance with this provision, the State Comptroller General will be notified.

Note: article repealed through article 12 1nd 13 of the External Resolution number RE- SERCOP-2016-000074 from December 23rd 2016.

**Art. 399.- Acceptance**.- The drugs reception will be made by two procedures:

1. **Technical acceptance**: For the technical acceptance of drugs, suppliers should deliver simple copies, in Spanish, of the following documents:

**a)** Health Registration Certificate valid in Ecuador.

**b)** Certificate of Quality Control Analysis of each batch, as provided in the law in force.

**c)** Authorization to import products by exception for drugs (in the case of drugs that do not have a Health Registration Certificate issued by the ARCSA).

The contracting entity shall verify that the drugs meet the requirements of the corresponding Technical Sheet of the drug.

2. **Administrative Reception**: According to the internal guidelines of each contracting entity, one or more delegates for receiving those medications may be appointed, who will control the amount requested and the qualifying documents, which are:

   **a)** Purchase Orders; and

   **b)** Invoice. After this, the acceptance of delivery-reception will be signed under the terms of Article

124 of the General Regulation of the Organic Law of the National Public Procurement System.

Reception of the drugs and their compliance with the technical sheets contained in the tender specifications, are the sole responsibility of the procuring health unit.

In the case of suppliers that are not based in Ecuador, they also should be responsible for local logistic in the distribution of catalogued drugs acquired by contracting entities.

**Art. 400.- Post Control.-** Each contracting entity, upon reception of the drug, will perform the post control Level 1 (technical reception), which shall encompass the verification of the technical sheets compared to the Health Registration.

In the event that the contracting entity considers necessary to make a post control Level 2 and /or Level 3, it shall request the competent entity for sampling and due analysis.

The levels of post control are the following:

1. Level 1: Verification of tertiary, secondary and primary packaging as well as the organoleptic characteristics of drugs.
2. Level 2: Qualitative analysis of the active ingredient.
3. Level 3: Qualitative and quantitative analysis of the active ingredient and microbiological control of the drug, or any other technical test required depending on the pharmaceutical form of the drug.

The cost of analysis Level 2 and Level 3 shall be borne by the supplier, who will replenish the number of samples used for the same.

If the results of the analysis of the post control Level 2 and / or Level 3, show no compliance with the technical specifications, the National Agency for Regulation, Control and Health Surveillance ARCSA -Spanish acronym- or the competent institution whichever that may be, shall notify about the results to the contracting entity, the National Public Procurement Service and the Health authority who shall apply the procedure and penalties within their scope of action.

Any irregularity in quality conditions identified in the drug, will involve the immediate suspension of the Agreement and the sanctions provided in the Law and its Regulations, without limitation of the execution of the appropriate guaranties.

Contracting entities must notify the contractors when a post control analysis of a drug is requested, listing the batch that is to be analyzed.

When contracting entities request a post control analysis of a batch that was previously analyzed, the contractor ought to deliver the aforesaid notification to the requesting entity, to avoid a new control of the same level.

**Art. 401.- Errors in the purchase order.-** If the purchase order generated by the entity shows inaccuracies or mistakes, the entity may annul the order within the following forty eight (48) hours after its generation, by means of an administrative act signed by the highest authority or his delegate, which shall be published in the institutional Website of the National Public Procurement Service.

In exceptional cases (as: issuance of an incorrect purchase order, duplication of a purchase order), with the agreement of the parties, a purchase order can be revoked after the term stated in this paragraph. The agreement should be executed by the maximum authority of the contracting entity that generated the purchase order or his/her delegate and by the supplier; this procedure should be notified to the National Public Procurement Service, independently of the obligation that has the contracting entity, the acquirer or issuer of the purchase order, of leaving evidence of the actions performed in the physical file as provided in articles 36 of Organic Law of the National Public Procurement System and 31 of its Regulations.

**Art. 402.- Levels of care.-** Health care institutions may acquire drugs through the Drugs e-Inventory, in accordance with the level of care and administrative capacity.

**Art. 403.- Suppliers Obligations.-** The signatories of the General Agreement are obligated to provide the drugs, according to the time, price, quality, delivery place and guarantee conditions established in the General Agreement and within the stated timeframe.

**Art. 404.- Expiration.-** Drugs should have an expiry date of more than 12 months at the time of reception, except for products which by their nature are degradable. If the delivered drugs are close to expire, the contracting entity shall notify the supplier, and it must proceed to exchange them in accordance with the provisions of Article 175 of the Organic Law of Health.

**Art. 405.- Health Registration.-** The Health Registration for each drug awarded in the Corporate Reverse Drugs Bidding shall be valid for as long as the drug remains listed in the Drugs e-Inventory, it is obligation and responsibility of the supplier to update it if the term is about to expire, with at least 60 day of anticipation. In the event that this certificate

expires, the drug will be taken out from the Drugs e-Inventory until the certificate is updated, which must be notified by the contractor through a letter addressed to the General Director of the National Public Procurement Service, requesting to update this information and attaching a copy of the certificate.

**Art. 406.- Price.-** The price offered by the contractor shall have a duration equal to the term of the General Agreement for all national territory and does not grant the right to any additional charge or payment.

**Art. 407.- Price Adjustment.-** If the prices of the drugs published in the Drugs e-Inventory change due to reforms in pricing policy, the following shall apply:

1. If the price of a drug is defined through a pricing policy, and that price is of lower value than the price awarded, the supplier must comply with the new price from the date of publication of that value, the same that shall be effective until the end of the General Agreement or until there is a new variation. To that value the provisions of Article 163 of the Organic Law of Health must be applied.

2. If the price of a drug is defined through a pricing policy, and that price is of higher value than the price awarded the contractor shall maintain the offered price until the end of the General Agreement or until there is a variation to a lower price, in which case it will be applied what is described above.

**Art 408.- Payment.-** Payments for acquisitions of medicines will be done with the funds from the budget allotments of each contracting entity or provider of health services; and they shall be made upon delivery, depending on the amount of medication actually delivered.

**Art. 409. Drug Exclusion.-** During the term of the General Agreement, the National Public Procurement Service periodically or at the request of the National Health Authority may review the drugs for human use and consumption that are offered in the Drugs e-Inventory, under the respective General Agreement, to determine the exclusion of any drugs. The contractor is not entitled to any conventional or judicial compensation if a drug is excluded.

## Section IV

## Procedure to regulate the alert system for drug quality control in the Corporate Reverse Drugs Bidding –SICM- purchased though the Drugs e-Inventory.

**Art. 410. Alert system for drugs quality control.** - The contracting entities that acquire medicines through the Drugs e-Inventory managed by the National Public Procurement System, as well as the suppliers of such drugs, shall be subject to the provisions of this Section, in order that the National Public Procurement Service, as contracting entity signatory of the Framework Agreement, take the necessary actions and measures to implement and assure the alert system for drugs quality control and the fulfillment of the technical specifications thereof.

**Art. 411.- Risks matrix.-** The methodology corresponding to the definition of the parameters to establish the quality controls through a risk-based analysis is included as Annex 10 hereof.

Based on the results established in the criteria and methodology of risk determined in this article, the drugs that will be submitted to quality control shall be identified.

**Art. 412.- Sampling techniques.-** The sampling methodology is included as Annex 11 of this Codification, which is based on the international standards contained in ISO / IEC 2859-1.

**Art. 413.- Inspection entity.-** It is an organization that through its technical competence accredited by the Ecuadorian Accreditation Service (SAE) or recognized by the National Public Procurement Service through the Operative Procedure PO09 R03 " *Evaluation for The recognition or designation of Conformity Assessment Entities* " of the SAE, will carry out the necessary activities for the application of the sampling methodology, sampling, transport of samples, maintenance of counter samples and coordination with laboratories accredited or recognized according to this Codification for the quality control of medicines.

The inspection entity shall not maintain absolute discretion and confidentiality of the information it knows on the execution of its activities, and may not disclose the identification of the laboratory where the respective tests of the medicine have been carried out.

This inspection entity shall directly invoice all expenses and costs that derive from the implementation of the actions that are carried out for the quality control alert system of medicines under this Section, to the Framework Agreement supplier.

The National Public Procurement Service, initially recognizes and only once, the inspection entities that have been accredited in analysis that include sampling systems. This

recognition is conditioned to the subsequent technical evaluation of the Ecuadorian Accreditation Service, until such entities are accredited in the specific scope. Subsequently, the procedures established for the recognition of the Ecuadorian Accreditation Service will be applied.

**Art. 414.- Recognition of inspection entities.-** The list of inspection entities is included as Annex 12 hereof in order to apply the provisions of the previous article of this Section. To this end, the inspection entity shall sign a legal written agreement with the National Public Procurement Service to establish the obligations and responsibilities of the parties under this Section. This list will be published in the Institutional Website of the National Public Procurement Service.

In the event that there are new accredited inspection entities that express their interest in participating in the "System of alerts for the quality control of drugs of the Corporate Reverse Drugs Bidding –SICM acronym in Spanish- acquired through the Drugs e-Inventory", they should send to the National Public Procurement Service such information, demonstrating its accreditation and interest, in order to carry out what was established in the previous section.

**Art. 415.- Inspection Entity Obligations.-** For the application of the system of alerts for the quality control of drugs, the inspection entity shall have the following obligations:

1. Conduct the sampling of the drugs, within a term not exceeding 72 hours, at the points requested by the National Public Procurement Service. Once this has been done, this National Service must be informed of what has been done in a 24-hour term;
2. Submit the samples taken to the laboratory that was selected to carry out the tests in a period not exceeding 48 hours;
3. Submit the certified reference material delivered by the General Agreement undersigned to the laboratory established by the National Public Procurement Service for the tests;
4. Keep in custody the counter sample withdrawn under the appropriate conditions established in the technical file of the drug during the shelf life of the batch;
5. Bill the supplier signatory of the General Agreement for the activities and services performed under this system of alerts for the quality control of drugs;
6. Make due payments to the laboratory accredited by the SAE and / or recognized by the National Public Procurement Service that has been selected for the analysis;

7. Deliver to the National Public Procurement Service copies of invoices issued to the General agreement signatory supplier for all the services performed under this system of alerts for quality control of drugs;
8. Maintain the necessary chain of custody, under the conditions specified in Annex 11 of this Codification, of the drugs delivered to the laboratories for the conduct of the tests; As well as maintain and comply with the storage and transport conditions contained in the medicine's technical file;
9. Visits and issue the report for the collection, distribution and storage centers of the health units of the Public Integral Health Network (RPIS) and / or storage centers of the Customs of Ecuador in which rest the drugs to be supplied to the RPIS and / or storage centers of the supplier that has signed the General Agreement, as determined by the National Public Procurement Service, to verify compliance with the storage conditions established in the technical sheets; and,
10. Other obligations agreed with the National Public Procurement Service.

**Art. 416. Costs assumed by the supplier signatory of the General Agreement and payment.-** The supplier signatory of the General Agreement, as contractual obligation, will be responsible for making the direct payment to the inspection entity for all actions or activities that involve quality control of the drug under this Section, once the invoice has been issued.

The costs to be covered by the supplier signatory of the General Agreement as part of the quality control alert system will the following:

1. Technical verification visits to the collection, distribution and storage centers determined by the National Public Procurement Service;
2. Activities of sampling and custody and maintenance of counter samples carried out by the inspection entity;
3. Tests performed in laboratories accredited by the Ecuadorian Accreditation
4. Service and / or recognized by the National Public Procurement Service;
5. Replacement in a time agreed with the health establishments, the samples and against samples of the medicines that are used for the quality control;
6. For the certified reference material (primary standard) of the drug to be carried out in the quality tests delivered to the inspection body:
7. For any other activity that involves quality control under this Section.

For the adequate traceability of the drugs delivered to the health units for which the provisions of this Section apply, the supplier must mandatorily indicate to the National Public Procurement Service the batch codes of the drugs that are delivered based on the purchase orders issued through the Drug e-Inventory.

The supplier will assume the costs of the items established in this article for the quality control of their drugs up to a value equivalent to 1.5% of the total value of the drugs required through the purchase orders issued through the Drugs e-Inventory at the date of sampling.

In order to control the value of the maximum amount to be assumed by the supplier established in the previous subsection, the inspection entity shall send copies of invoices issued for its activities and services under this Section to the National Public Procurement Service, as well as the invoices for the services provided by the laboratories conducting the tests and technical tests.

**Art. 417.- Recognized or accredited laboratories.-** Is the entity in charge of performing the tests and technical tests to the drugs to evaluate the conformity with the contractual object established in the General Agreement; i.e. compliance of the active ingredient in terms of concentration, pharmaceutical form and established presentation, as well as the relevant conditions specified in the product's technical file. The laboratories will be accredited by the SAE and / or recognized by the National Public Procurement Service.

The National Public Procurement Service recognizes initially and only onc the laboratories that have been accredited in a particular instrumental technique, conditioning this recognition to the subsequent technical evaluation of the Ecuadorian Accreditation Service, until such laboratories are accredited in the specific scope. Subsequently, it should be applied what is established in the procedure for the SAE recognition.

**Art. 418.- Recognition of laboratories.-** The list of laboratories is included as Annex 13 hereof to apply the provisions of the previous article of this Section. This list will be published in the Institutional Website of the National Public Procurement Service. To this end, the laboratory shall sign the legal written agreement with the National Public Procurement Service to establish the obligations and responsibilities of the parties under this Section.

In case there are new accredited laboratories that show their interest in participating in the "System of alerts for quality control of the drugs of the Corporate Reverse Drugs Bidding - SICM (acronym in Spanish)- acquired through the Drugs e-Inventory" they should send to the National Public Procurement Service the aforementioned information, which demonstrates its accreditation and interest, in order to carry out what is established in the previous section.

**Article 419.- Supplementary sampling for international reference laboratories.-** The National Public Procurement Service will ensure that the analyzes, tests and technical tests for the system of alerts for quality control of the drugs are carried out with national and international laboratories. For the latter case it will be carried out with laboratories

The National Public Procurement Service will pay for the analysis, tests and technical tests for quality control of drugs carried out with accredited international laboratories.

**Art. 420.- List of tests.-** The list of tests is included as Annex 14 hereof for the alert system for quality control of the drugs of the Corporate Reverse Drugs Bidding, which is based on the Pharmacopoeia of the United States (United States Pharmacopeia, USP) and the international standard referred to by the World Health Organization

**Art. 421.- Prices.-** The inspection, sampling and counter sampling of medicines and other services performed by the Inspection Entities within the framework of this Section, as well as the performance of tests by laboratories for the system of alert for quality control of drugs, must refer to the list of prices that the National Public Procurement Service will publish in its Institutional Website, which will represent the maximum values of mandatory compliance by the laboratories. This list of reference prices must be included in the respective legal instrument that both Inspection Entities and laboratories sign with the National Public Procurement Service for recognition as entities competent to participate in the "Quality Control Alerts System for the drugs of the Corporate Reverse Drugs Bidding - SICM (acronym in Spanish)- acquired through the Drugs e-Inventory.

The reference prices established in this article may be revised and adjusted only by the National Public Procurement Service, which will be published in the Institutional Website of the National Public Procurement Service.

**Art. 422.- Results of tests.-** Both the inspection entity and the laboratories will be responsible for submitting a copy of the results of the drugs quality controls through the

system of alerts to the National Public Procurement Service, RPIS and the National Agency for Regulation, Control and Health Surveillance (ARCSA) immediately, i.e., within 15 days after the laboratory has received the sample by the inspection entity. The results, as alerts, will be posted in the Institutional Website of the National Public Procurement

**Art. 423. Procedure for submission of results.-** Once the National Public Procurement Service receives the quality control result in accordance with the provisions of the previous article, it shall request the ARCSA to carry out the review or confirmation of such results to take the actions or sanctions in the relevant cases.

Notwithstanding the foregoing, once the review or confirmation has been made, the ARCSA must submit the results to the National Public Procurement Service, in order to apply proper actions or sanctions.

**Art. 424.- Sanction by the National Public Procurement Service.-** The National Public Procurement Service may apply the sanctioning procedure based on the results of the tests of the system of alert for quality control of the drugs performed by accredited Laboratories or those recognized by the National Public Procurement Service or by the ARCSA. These results will be binding to the sanctions regime established by the Organic Law of the National Public Procurement System, its General Regulations, and the provisions to regulate the procedure of Corporate Reverse Drugs Bidding, General Agreements and this Section.

When, as a result of the tests or technical tests carried out under this Section, an alert is established that the medicinal product is not in conformity with the contractual object and its technical file, the National Public Procurement Service may suspend indefinitely the medication in the Drugs e-Inventory in order to protect the health of the citizens, until obtaining a result of second instance or until the results of control of the medicine by the ARCSA are obtained.

In the event that the sanction established in this article is applied to the supplier signatory of the General Agreement and that such sanction results in the early and unilateral termination of the General Agreement, the National Public Procurement Service may directly contract the acquisition of the drug with one of the bidders that participated in the bid according to The procedure established in the provisions to regulate the procedure of the Corporate

# Reverse Drugs Bidding.

NOTE: "This is a translation form the original version in Spanish. This translation is for information purposes only and has no legal value. All legal and/or binding documents shall be executed and/or interpreted form the official version only, which is the original Spanish version".