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 interpreted form the official version only, which is the original Spanish version".

RESOLUTION No. RE-SERCOP - 2016-000044
GENERAL DIRECTOR'S OFFICE
NATIONAL PUBLIC PROCUREMENT SERVICE

CONSIDERING:

Whereas Article 286 of the Constitution of the Republic of Ecuador provides that public finances, in all government levels, shall the managed in such a way that would be sustainable, responsible and transparent and shall seek economic stability. Fixed expenditures shall be financed with fixed income. Fixed expenditure for health, education and justice shall be prioritized and by exception can be financed with non fixed income;

Whereas Article 32 of the Constitution of the Republic of Ecuador states that health is a right guaranteed by the Government through economic, social, cultural, educational and environmental policies; as well as access to programs, actions and promotional and comprehensive health services, sexual health services and reproductive health services in a permanent and timely manner, and without exclusion. The provision of health services shall be governed by the principles of equality, universality, solidarity, multiculturalism, quality, efficiency, effectiveness, prevention and bio-ethics, with a focus on gender and age fairness;

Whereas numeral 7 of the Article 363 of the Constitution of the Republic of Ecuador states that the Government shall be responsible of guarantying the availability and access to good quality, safe and effective medication, regulate their marketing and promote local production and the use of generic drugs that meet the epidemiologic needs of the population. In the access to medication, the interests of public health shall prevail over economic and commercial ones;

Whereas the Organic Law Reform to the Organic Law of the National Public Procurement System, published in Official Gazette No. 100 of October 14, 2013, created the National Public Procurement Service, as a statutory body, technical authority, and independent legal person, with administrative, technical, operational, financial and budgetary autonomy. Its senior and legal representative is the General Director;

Whereas Article 9 of the Organic Law of the National Public Procurement System states that the Government's main objectives, in the area of public procurement, are to ensure the

quality of the public expenditure and its performance in accordance with the National Development Plan, maintain and follow effective public procurement planning and budgets systems of the National Regional Governments, encourage and guarantee the participation of the Central and Regional governments and their budgets, and encourage and guarantee the participation of reliable and competitive suppliers in the National Public Procurement System;

Whereas Article 4 of the Organic Law of the National Public Procurement System provides that for the application of this Act and the contracts derived therefrom, they must comply with the principles of legality, fairness, equality, quality, technological effectiveness, opportunity , competition, transparency, publicity and national participation;

Whereas paragraph II, Section II, Chapter VII, Title III of the Regulation to the Organic Law of the National Public Procurement System establishes the procedure for acquiring drugs by Corporate Reverse Bidding;

Whereas by Executive Decree No. 648 of March 25th, 2015, the senior authority of the National Public Procurement Service is appointed, (SERCOP- acronym in Spanish);

Whereas by Resolution No. 057-2012 of March 7th, 2012, the General Director of SERCOP resolved to issue the instructions for the procurement of drugs through the Drugs e-Inventory;

Whereas by Memorandum No. SERCOP-DE-2013-0059-M of April 2nd, 2013, the General Director of SERCOP commanded the Director of Regulations of the National Legal Department Coordination, under the supervision of its representative , and in collaboration with the Technical Operations Coordinator, to prepare and approve an instructions manual to regulate and govern the procedure to be followed in the management of the Corporate Reverse Biddings that SERCOP is to carry out;

Whereas in the General Inter-Agency Agreement No. 000017 of April 10, 2015, guidelines and coordination mechanisms were issued, which should be complied by the parties (Ministry of Interior, Ministry of National Defense, Ecuadorian Social Security Institute, Social Security Institute of the Armed Forces, Social Security Institute of the National Police and the Ministry of Public Health) for the articulated operation of the Public Integral Health Network - (RPIS - acronym in Spanish);

Whereas by meeting held in August 28th 2015 as it is stated in the "proceedings of the session for the approval of the Instructions to norm the procedure of the Corporate Reverse Drugs Bidding"; and

In use of its legal and regulatory powers,

DECREES:

ISSUING INSTRUCTIONS TO NORM THE PROCEDURE OF THE CORPORATE REVERSE DRUGS BIDDING

CHAPTER I
OVERVIEW

Art. 1.- Application Scope.- This instructions are meant to norm the procedure for the Corporate Reverse Drugs Bidding , which is conducted by the National Public Procurement Service -SERCOP-, and the members of the Public Integral Health Network -RPIS- composed by: -MSP- Ministry of Health, Social Security Institute of the Armed Forces -ISSFA-, Social Security Institute of the National Police -ISSPOL- and Ecuadorian Social Security Institute -IESS-; for the purchase of medicines for human use and consumption, published through the institutional Website of the SERCOP under Drugs e-Inventory, www.sercop.gob.ec.

Art. 2.- Definitions.- For the purposes of this instruction, the following definitions shall apply:

2.1. Awarded Bidder.- Is the natural or legal, Ecuadorian or foreign person who is registered and enabled in the Registry of Suppliers (RUP), who has complied with the terms and conditions of adherence, has ended up as winner of the biding or negotiation stage, as applicable and has submitted all required documentation in time according to Tender Specifications, and after the verification of it, the maximum authority of SERCOP or his/her delegate grants this person the right and duties by the execution of the General Agreement for the provision of medicines for human use and consumption through the Drugs e-Inventory.

2.2. Access Password.- Personal password to the institutional Website of SERCOP, through which participants are to be registered as suppliers and have access to the IT tool that allows them to participate in the Corporate Reverse Bidding for Drugs.

The access password is of exclusive use and responsibility of the supplier., All actions performed through the institutional Website of SERCOP are to be guaranteed and legalized

through the username and password.

At all times, the supplier shall be responsible for maintaining the secrecy of his accounts numbers, personal passwords, access codes and confidential numbers that allow access the Official System for National Procurement (SOCE - acronym in Spanish) and other services under the institutional Website of SERCOP.

2.3. Unique Drug Code (CUM - acronym in Spanish).- It is the identifying code with which a drug is sold in the county, for traceability purposes. It is made out of alphanumeric characters that communicate the active ingredient, its pharmacological action, pharmaceutical form and concentration among other characteristic.

2.4. Drugs Advisory Board.- Are advisory mechanisms, made by citizen, or civil organizations, which constitute spaces and advisory bodies referred to in the Law of Citizen Participation and Social Control, which can have various approaches, under the scope that it is applied, as in the specific case of drugs, it is aimed to listen to all stakeholders, citizens, academia, international experts, and other productive and social players involved in the production, marketing, distribution and consumption of medical drugs.

2.5 International Nonproprietary Name.- Generic name or active ingredient for each drug.

2.6. Negotiation.- Meeting between the Technical Commission, on behalf of the contracting entities and the bidder, in order to better the price proposed in the initial financial offer made by the bidder, which should decrease at least 5% from the referential budget.

2.7. Offer.- Is the electronic form by which the supplier expressly declares and accepts the terms and conditions of adherence, specifications contained in the technical sheets of the drug; commercial, economic and legal conditions laid down in the tender specifications, which allow bidders, by means of their password in the institutional Website of SERCOP, to participate in the Corporate Reverse Drugs Bidding .

2.8.Winning Offer.- Offer that has the lowest price in the bid or that reaches a favorable negotiation for the entity. For this offer to be awarded, it shall fulfill the requirement such as submission of Terms and Conditions of Adherence, specifications of the technical sheet of the drug, commercial, economical and legal conditions set out in the Tender Specifications.

2.9. Initial Economic Offer.- Economic proposal that is submitted by a bidder once

submitted his/her offer (electronic form of adhesion) through the institutional Website of SERCOP, prior to his/her participation in the phase of negotiation or bidding, as deemed appropriate, which shall be lesser than the referential budget per unit of the drug for at least 1%.

2.10. Purchase Order.- Instrument through which the procurement of drugs for human use and consumption is formalized through the Drugs e-Inventory. In the Purchase Order the contracting entities providers of health services, establish the purchasing conditions, amount and place of delivery for the drugs required. The selected supplier is obliged to comply with these conditions as it is provided in the General Agreement.

2.11. Referential Budget per Unit.- Is the value per unit of each drug that will be published in the procurement procedure of the Corporate Reverse Drugs Bidding, that suppliers shall use as reference to enter the initial economic offer, the reverse bidding or the no participation, as appropriate.

2.12. Tender Specifications.- Pre-contractual document prepared and approved by the SERCOP and the Public Integral Health Network members, for the process of the Corporate Reverse Drugs Bidding.

2.13. Bid.- Mechanism by which bidders of the procedure of Corporate Reverse Drugs Bidding, submit through the institutional Website of SERCOP their economic offers, and in accordance to the death line set out in the schedule of the tender specifications, bidders compete with a downward trend until they reach the minimum price.

2.14. Public Integral Health Network (RPIS- acronym in Spanish).- Articulated set of public health care institutions which are part of the Ministry of Public Health -MSP-, Social Security Institute of the Armed Forces -ISSFA- Social Security Institute of the National Police -ISSPOL- and, Ecuadorian Social Security Institute -IESS-.

2.15. Drugs e-Inventory (RM - acronym in Spanish).- Electronic catalog of standard drugs published in the institutional Website of SERCOP for direct procurement as provided in the General Agreements by the entities that are part of RPIS.

2.16. Calculation of death lines and terms.- For the application of these instructions, tender specifications and the procedure for Corporate Reverse Drugs Bidding, when displayed the days as working days, they will be understood as working days, that is, it will be excluded from the calculation of days Saturdays, Sundays and those days considered as holydays.

When the days are expressed as term, the calculation of the days will include working days,

Saturdays, Sundays and holydays.

Art. 3. Information Update of Registry of Suppliers.- 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 SERCOP until 48 hours before the end of the stage of offer submission (electronic form of adhesion).

Art 4.- Verification for suppliers.- SERCOP 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 SERCOP 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.

CHAPTER II
PROCEDURE FOR CORPORATE REVERSE DRUGS BIDDING .

Art. 5.- 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:

5.1. 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.

5.2. The General Deputy Director, the Research Department, Risk Department and the Department of Electronic Catalog, shall coordinate 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 SERCOP;

5.3. 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 SERCOP for approval;

5.4. The Technical Directorate of Technological Innovation and its Departments, shall publish on the website, 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 date of consultation.

5.5. 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 SERCOP, 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;

5.6. The Directorate of Planning and Strategic Management in conjunction with the Project Leader will inform immediately in writing the General Director of SERCOP 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 Corporate Reverse Drugs Bidding.

5.7. The Legal Advisory Department of SERCOP shall advice in all legal issue to the Technical Commission during the implementation of the procedure of the Corporate Reverse Drugs Bidding; and by request of it shall issue legal reports.

5.8. 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.

5.9. The Technology Directorate, 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 SERCOP takes appropriate decisions.

5.10. 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 SERCOP, to take the necessary measures to extend these costs, by the execution of General Agreements to the other Contracting Entities.

5.11 RPIS members will officially inform the General Director of SERCOP 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.

5.12. RPIS members will officially inform the General Director of SERCOP about the distribution of drugs, object of the Corporate Reverse Drugs Bidding, for each health unit that is part of the RPIS.

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

5.14. The National Agency for Regulation, Control and Health Surveillance (ARCSA - acronym in Spanish) will inform the General Director of SERCOP about the pharmacovigilance mechanisms and post control.

Art. 6.- 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 LOSNCP. The Coordinator of SERCOP's Law Advisory or his delegate will act as secretary.

The Technical Commission is responsible for:

a) 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.

b) 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.

c) Will give the General Director of SERCOP, 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 SERCOP or his/her delegate can decide.

d) Issue a report to the General Director of SERCOP, or his/her delegate, about the list of drugs that haven't been awarded, so that due actions are taken according to the LOSNCP, its Regulations and Resolutions for the objective set by SERCOP;

e) Evaluate that suppliers have entered their offer through the electronic form of adherence to the terms and conditions of Tender Specifications.

f) Prior issuing the Report of Recommendation to Award the Contract or to declare it void due to no-show, according to the case, will ask the Registration and Customer Service Department a report about the situation of the bidders that are winners of the bid or the negotiation.

g) To issue minutes of each step of the procedure.

h) If required, request the General Coordination of Legal Advisory of SERCOP legal advice during the Corporate Reverse Drugs Bidding.

i) Others prescribed by the norm or tender specifications.

Art. 7.- Publication of Tender Specifications and Invitation.- SERCOP shall perform the publication of the invitation and Tender Specifications in Spanish and English, being

the official version the Spanish one, through the institutional Website of SERCOP.

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. 8.- Questions, answers, clarifications or modifications.- Bidders, through the institutional website of SERCOP, 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 SERCOP 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. 9.- Offer.- Through the institutional Website of SERCOP, 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 SERCOP 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 SERCOP, 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 SERCOP 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 SERCOP 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, so 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. 10.- Evaluation.- The Technical Commission shall have, by means of the Official System for National Procurement, a report of the enabled bidders to evaluate the submission and acceptance of the electronic form of adhesion through the institutional website of SERCOP, which shall let them enter their initial economic offer.

Art. 11-. Initial Economic Offer.- Bidders prior engaging in the bid or negotiation session, as appropriate, shall send their initial economic offer through SERCOP's institutional Website within the time period provided by respective tender specifications.

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

Art. 12.- 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 with 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. 13.- 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 present their positions trending downwards with respect to the initial economic offer, respecting the minimum range of variation for the bid price set out in the tender specifications.

The initial economic offers submitted through the institutional Website of SERCOP 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 SERCOP shall automatically reschedule the reverse bid, only once, within the next 24 hours.

Every enabled supplier for the bidding phase, that has submitted its initial economic offer and does not participate in the reverse bid despite the rescheduling of it, will commit the offense under paragraph d) of article 106 of the Organic Law National Public Procurement System in accordance with the procedure laid down in Article 108 of aforesaid Act.

In those cases where there were at least two bidders for the bid phase and despite the rescheduling a reverse bid has not taken place, the contracting entity shall declare it as a void procedure due to no show and shall initiate a new one, without limitation of the appropriate penalties.

The Official System for National Procurement –SOCE, once the bid is finished, will select the best economic bid based on the lowest price among the bidders that participated with their offers.

Art. 14.- 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. 15.- Negotiation.- For the Corporate Reverse Drugs Bidding there shall be negotiations in the following cases:

a) In the cases where 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.

b) If any initial economic offer of a supplier that did not participate in the rescheduled bid, as provided in the article 12 of these instructions, was less that the offer of the unique bidders that participated in it, such unique bidder shall go to a negotiation meeting and set the value of the negotiation offer at least equal to the lowest value submitted before the bid, and from this value the negotiation shall begin; the value can't be less than the 5% of the value of the referential budget per unit. If there is no negotiation, the procurement procedure shall be declared as void due to no show.

In both cases of negotiation there shall be written evidence in a memo signed by the parts and it shall be published in the institutional website of SERCOP.

Once performed a successful negotiation meeting, and published the result in the institutional Website of SERCOP, 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. 16.- Presentation and verification of documentation.- The supplier winner 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 SERCOP, that has been specifically requested in the tender specifications as prerequisite to be awarded. 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 SERCOP or his representative to initiate the procedure laid down in Article 108 of the LOSNCP 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 who has the documentation immediately (72 hours) and 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 SERCOP or his / her delegate shall declare the selection procedure void due to no show, with no limitation of the administrative penalties applicable.

Art. 17.- 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

SERCOP or his / her delegate, where it will be noted that the bidder meets the requirements of the tender specifications, the highest authority of SERCOP 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 SERCOP.

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

1. Fulfillment of the requirements of tender specifications and technical sheets
2. Report of the awarded price, obtained through the SOCE. In case of negotiation, the negotiation minute should be exhibited

Art. 18.- Penalties for false information.- If the Technical Commission or the highest authority of SERCOP 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 SERCOP General Director 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. 19.- Drugs Indexation.- In a term of five (5) days after the execution and registration of the General Agreement, the SERCOP will publish in the Drugs e-Inventory available in the electronic catalog, the drug that was the object of the Bidding contest, so that is to be purchased in a mandatory and exclusive way by the entities that provide health services, though the use of this tool.

CHAPTER III

USE OF GENERAL AGREEMENT AND PURCHASE ORDERS THROUGH DRUGS E-INVENTORY

Art. 20.- 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 SERCOP 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) and photographs 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 receiving 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 once every three months.

Art. 21.- Acceptance.- The reception of medicines will be made by two procedures:

a) Technical acceptance: For the technical acceptance of drugs, suppliers should deliver simple copies, in Spanish or English, of the following documents:

- Health Registration Certificate valid in Ecuador.
- Certificate of Quality Control Analysis of each batch, as provided in the law in force.

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

b) 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:

- Purchase Orders; and
- 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.

Receiving of the medications 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. 22.- Post Control.- Each contracting entity, upon reception of the drug, will perform the post control Level 1 (technical receiving), 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:

- Level 1: Verification of tertiary, secondary and primary packaging as well as the organoleptic characteristics of drugs.
- Level 2: Qualitative analysis of the active ingredient.
- 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, SERCOP and to the Health authority who shall apply the procedure and penalties within their scope of action, as shall ARCSA too.

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 warranties.

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. 23.- 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 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 SERCOP.

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 SERCOP, 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 LOSNCP and 31 of its regulation.

Art. 24.- Levels of care.- The care institutions of health may acquire drugs through the Drugs e-Inventory, in accordance with the level of care and administrative capacity.

Art. 25.- 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. 26.- 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. 27.- 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 SERCOP, requesting to update this information and attaching a copy of the certificate.

Art. 28.- Price.- The price offered by the contractor shall have a duration equal to the General Agreement term for all national territory and does not grant the right to any additional charge or payment.

Art. 29.- Price Adjustment.- If the prices of medicines that are published in the Drugs e-Inventory change due to reforms in pricing policy, the following shall apply:

- 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.

- 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 30.- 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. 31. Drug Exclusion.- During the term of the General Agreement, the SERCOP 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.

GENERAL PROVISION.-

From the issuance of this document, the Technical Operations Coordination is delegated with the responsibility of the implementation of all records, forms and online access in the institutional Website of SERCOP, to fulfill the procedure of Corporate Reverse Drugs Bidding that is regulated by means of this resolution.

REPEAL.-
It is Repealed SERCOP's Resolution No. 057-2012 of March 7th, 2012.

FINAL PROVISION.-
This resolution will take effect from its execution and publication in the institutional Website of SERCOP without prejudice to its publication in the Official Gazette.

Executed in the city of Quito M.D, on January 11th, 2016

Ec. Santiago Vásquez Cazar
GENERAL DIRECTOR
NATIONAL PUBLIC PROCUREMENT SERVICE

Hereby I certify that thereto resolution was executed and approved today, January 11th, 2016

Dr. Hugo Estrada Proaño
DOCUMENT MANAGEMENT AND ARCHIVE DIRECTOR
NATIONAL PUBLIC PROCUREMENT SERVICE