

AGREEMENT

1. INTRODUCTION

1.1 Preamble

The UNION, though the AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA (NATIONAL HEALTH REGULATORY AGENCY), hereinafter referred to as ANVISA, registered under CNPJ number 03.112.386/0001-11, based at SIA Trecho 05, Special Area 57 – 71.205-050 – Brasília/DF, herein represented by its Acting Director President, FERNANDO MENDES GARCIA NETO, CPF: 026.358.598-09 and the UNITED NATIONS OFFICE ON DRUGS AND CRIME, hereinafter referred to as UNODC, based at The United Nations Headquarters 405 East 42nd Street, New York, NY 10017, USA, represented by its Regional Office in Brazil, at SCS Quadra 2, Ed. Serra Dourada, suites 410-418, Brasília/DF, registered under CNPJ number 05.826.921/0001-21, herein represented by RAFAEL FRANZINI BATLLE, CPF: 704.111.001-06, agree on the present Service Level Agreement.

This agreement is regulated by the basic agreement for Technical Assistance (in Portuguese, Acordo Básico de Assistência Técnica, ABAT), which provides the basis for technical cooperation by the United Nations in Brazil. The ABAT was signed on December 29, 1964 between the Government of the Federative Republic of Brazil, the United Nations and its Specialized Agencies, approved by Legislative Decree no. 11, of 1966 and promulgated by Decree no. 59.308 of September 23, 1966.

1.2 Purpose and Objectives

This document serves as a Service Level Agreement between
the **CLIENT:**

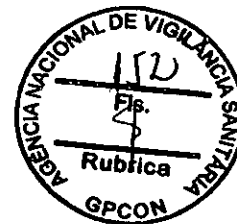
AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA - ANVISA (hereinafter referred to as the *Client*)

And the **SERVICE PROVIDER:**

The United Nations Office on Drugs and Crime, Enterprise Application Center – Vienna (EAC-VN)
(hereinafter referred to as UNODC)

on the continuous deployment and support of Drug Control System - NDS *Program Suite* (including NDS 7, NDS SPA, NDS Extweb, NDSWEB and NDS – I2ES integration client)

Over the last century, a worldwide system for control of drugs of abuse has developed gradually through the adoption of a series of international treaties. The important multilateral conventions currently in force are the Single Convention on Narcotic Drugs of 1961 as amended by the 1972



Protocol; the Convention on Psychotropic Substances of 1971 and, adopted in 1988, the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Each successive treaty brought complementary regulations and advances in international law. From the beginning, the basic aim of the international drug control treaties has been to limit the use of drugs to medical and scientific purposes only.

A computer-based system, Computer and Telecommunication System for International and National Drug Control (NDS), has been designed and developed by the United Nations, to assist Member States and is available to facilitate management and control over licit movements of psychoactive drugs and precursor chemicals and to enhance timeliness of information exchange at the national and international levels. NDS can be utilized to fulfil varying national drug control management needs. It can be used to:

- Facilitate form preparation, in both printed and electronic formats, for the reports to be submitted to the Secretary General according to the requirements outlined in the international drug control conventions.
- Facilitate national drug control information management.
- Facilitate both national and international drug control information exchanges through electronic medium.

Considering the Agreement initially signed in March / 2014 between Anvisa and the United Nations Office on Drugs and Crime (UNODC), for the implementation and installation of the NDS system, as well as for maintenance and support in the period of three (3) years, we emphasize the importance of the continuity of the NDS system so that the established activities are maintained in order to strengthen the control and the exchange of information provided by the NDS system to date.

The purpose of this SLA is to formalize a new agreement between the UNODC and the Client, aiming at the continuity and maintenance of the NDS Program Suite, configure it to specific needs, provide training in its use to selected end-users and provide maintenance services as specified in this SLA.

1.3 Agreement to Terms

These terms and conditions shall govern all services by UNODC to the Client. Except as expressly provided herein, this SLA supersedes all prior or contemporaneous SLAs or Agreements, oral or written, and any other understandings between UNODC and the Client relating to the subject matter of this SLA.

1.4 Definitions

For the purposes of this SLA, the following terms shall have the following meanings:

National Drug Control System - NDS	<i>Program Suite</i> : is an comprehensive IT-based solution, developed by UNODC for use by member states;
Product	the National Drug Control System - NDS <i>Program Suite</i> application;
Related services	those services performed by UNODC (or its representatives) under this SLA;
Software	any computer programs, operating system and firmware incorporated into the general IT environment;
Business Day	Monday through Friday from 09:00 to 17:00 (GMT + 1), official United Nations holidays excluded;
UNODC	United Nations Office on Drugs and Crime
EAC-VN	Enterprise Application Center – Vienna.

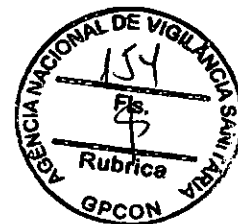
1.5 Parties to the SLA

The United Nations Office on Drugs and Crime, Enterprise Application Center – Vienna (EAC-VN) is the provider of the National Drug Control System - NDS *Program Suite* and related services.

Agência Nacional de Vigilância Sanitária - ANVISA are the recipient of the National Drug Control System - NDS *Program Suite* application and related services.

Therefore, UNODC and ANVISA are the parties to this SLA and have agreed as follows:





2. SCOPE OF WORK

2.1 Services Rendered by UNODC to the Client

2.1.1 Business Analysis, Architecture and Systems Design – N/A

2.1.2 Software Configuration Services

- a) Configuration of the NDS Program Suite application including database schema configuration, and web services
- b) Configuration of Website(s) and data collection tools
- c) Guidance on legacy data migration or integration with legacy systems. This does not include the provision of full data migration services

2.1.3 Installation, Maintenance and support

- a) Initial installation (a preproduction on-site installation of updated versions of which includes installation, configuration in a preproduction environment as well as training of staff on configuration and migration tasks) and configuration of system hosted on servers operated by the Client
- b) Installation and configuration of the NDS Program Suite application and its updates including database schema installation and configuration, and web services
- c) Maintenance services and regular updates to the system during the maintenance period
- d) Second and third level support for issues occurred in day-to-day operation of the system, rendered by email / chat, phone or remote PC control.
- e) Within the duration of the SLA, provision of one on-site support visit per calendar year to Client's site for a maximum duration of two calendar weeks per year by support staff from UNODC, depending on the need and at the request of the Client and at a time suitable to both parties

2.1.4 Capacity Building

- a) User training sessions; one session for IT personnel and the other for drug control experts and management. The training will be delivered by the UNODC present at the Client's site
- b) NDS user manuals, technical documentation and help files will be provided and assistance how to configure it to national needs (e.g. translation)



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2.2 Services Not Covered by UNODC

- a) Verifying correctness of any information being processed using the system
- b) Data migration from legacy systems
- c) Installation, configuration and operation of infrastructure required to operate National Drug Control System - *NDS Program Suite*

2.3 Responsibilities of the Client

- a) Ensure that IT environments are made available as per UNODC specification
- b) Ensuring that any support needed by the Client or the *NDS Program Suite* end users is channeled to UNODC through the agreed *NDS Program Suite* Task Force, which the Client will create (Terms of Reference of the GTF will be sent separately) to ensure a smooth transfer of data and knowledge. The Client will provide full on-site and remote access, if required, for *NDS Program Suite* installation and related support, to UNODC personnel as and when required to enable the effective and efficient implementation and maintenance of the *NDS Program Suite*. The *NDS Program Suite* Task Force should follow the protocol described in section 5.2 Support Procedure, when escalating problems to the UNODC support and maintenance team.
- c) Assist and work together with UNODC regarding all matters related to the functional specification.
- d) Participate in the testing and validation phases of all work done by UNODC.
- e) Train end users staff after the deployment phase in the use of the system.
- f) Create training material on new system.

2.4 Commencement Date

The commencement date for the delivery of services will be on a mutually agreed date, following the signing of this SLA and receipt of the full payment of the first year's support and maintenance fee, as indicated in section 4.2 *Payment Schedule*, by UNODC.

2.5 Duration of the Agreement

The initial duration of this SLA is five (5) years starting from the mutually agreed implementation start date after the signing of this SLA by both parties and receipt by UNODC of the full payment of the installation fee and the first year's support and maintenance fee as indicated in section 4.2 *Payment Schedule*.



3. PERFORMANCE MEASURES

- a) UNODC and Client Focal Points shall engage in regular meetings, at a frequency to be mutually agreed on, to discuss the implementation and usage progress as well as any impediments faced.
- b) Over the period of this agreement, UNODC shall implement performance reporting as may be required by providing the Client with all available system performance reports and records.

4. PAYMENT CONDITIONS AND SCHEDULE

4.1 Payment Conditions

- a) The currency of resources under this Agreement is USD.
- b) In consideration of the services to be provided by UNODC pursuant to this Agreement, the Client shall render resources to UNODC as outlined in section 4.2 *Payment Schedule*.
- c) UNODC shall not perform any other services that may result in charges to the Client over and above the amounts set out in section 4.2 *Payment Schedule* without the written authorization of the Client.
- d) All travel, terminal expense and daily subsistence costs incurred in the delivery of the above services are included in the fees agreed under the terms of this Agreement.
- e) As per the Service Delivery Cost Recovery Principle it is required that funds for the NDS Program Suite are made available prior to services being rendered. Consequently, no service delivery will start prior to the cash transfer.
- f) UNODC will review the actual costs of the services delivered and adjust the budgeted costs to the actuals via a debit/credit memo, noting that no additional funding will be required from the client outside the conditions mentioned in point g) below.
- g) In case of additional requests by the Client, not foreseen under the scope of work as stipulated in this agreement, or in case of major cost changes due to exchange rate fluctuations, UNODC will notify the Client about additional funding requirements and request the written authorization of the Client for all expenses in excess of the budget above-mentioned, within one month of the identification of the additional funding



requirements. If no such further funding is made available, the additional services requested by the Client may not be possible. In no event, will UNODC assume any liability in excess of the funds provided.

- h) Delays due to the Client missing agreed response deadlines may result in additional UNODC charges. UNODC will consult with and obtain written approval from the Client prior to incurring any such additional charges as specified in chapter 8.5 Liability as to Costs.
- i) All amounts are indicated with Administration Fee (13 % of total).
- j) ANVISA shall deposit the funds mentioned to the following bank account, designated by the UNODC Regional Office:

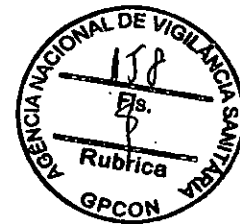
Title of account: Escritório das Nações Unidas sobre Drogas e Crime
 Tax ID: 05.826.921/0001-21
 Address: SCS Qd 02, Bloco C, Ed. Serra Dourada, salas 410/418, Brasília, DF
 Bank name: Citibank S/A
 Bank number: 745
 Bank branch/agency: 008
 Bank account number 3806200

- k) The cost of this contribution/donation shall be made from the following budget:
 Internal Plan: 18GGMON0001
 Nature of Expense:
 Commitment Note: (to be completed later on the process)

4.2 Payment Schedule

Date	Purpose of payment	Amount
Within 30 days of signature of the SLA	Year one support and maintenance fee	57 461 USD
On the anniversary of the first payment	Year two support and maintenance fee	57 461 USD
On the anniversary of the second payment	Year three support and maintenance fee	57 461 USD
On the anniversary of the third payment	Year four support fee and maintenance fee	57 461 USD





On the anniversary of the fourth payment	Year five support fee and maintenance fee	57 461 USD
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4.3 Invoice Address

SIA Trecho 5, Área especial 57
CEP: 71205-050
Brasília (DF) - Brazil

5. DUTIES AND RESPONSIBILITIES

5.1 Support Availability

The UNODC Service Desk shall be available 07:00 – 19:00 (GMT+1) Monday to Friday and on a best effort basis outside office working hours.

5.2 Support Procedure

The support line is reachable by email on service.desk@unvienna.org , and by phone on (+43-1) 26060-4200. All requests for support shall be submitted on the support website - <https://gosupport.unodc.org> must be sent by e-mail. The e-mail must contain an adequate description of the nature of the support required.

5.3 Response Time

UNODC shall respond to a request for support made pursuant to clause 5.2 above within two business days of receipt of an emailed description or ticket of the nature of the support required. The timing of the delivery of an answer shall depend on the nature of the support required.

5.4 Delivery of Support Solution

The delivery of a solution to a support request as referred to in clause 5.3 is concluded by an emailed response or relevant reply in ticketing portal from Client, declaring that the quality of the solution provided has been satisfactory. In the event that no response is provided by Client within five business days of the delivery of an answer by UNODC, the solution shall be considered as satisfactory.





5.5 Responsibility of the Client Regarding Technical Problems

Any technical issues encountered in the Client's operating environment for systems not related to the National Drug Control System - *NDS Program Suite*, including printing, networking and operating systems are not covered by this SLA.

It remains the Client's full responsibility to ensure adequate protection against loss and improper use of data and unauthorized access to systems.

5.6 Responsibility of UNODC Regarding Technical Problems

Any problems related to the National Drug Control System - *NDS Program Suite* software during its operational use in the production environment shall be analyzed by the UNODC support team, which will provide guidance and support. Any recommendations shall be mutually agreed upon and implemented through appropriate means.

UNODC may access any system or any data of the Client through remote access at the specific request of the Client, for purposes and under conditions specifically required and stipulated by the Client and under the direct supervision of the Client.

UNODC does not take responsibility for loss, improper use or corruption of data arising from any causes beyond its control.

5.7 Access to the National Drug Control System - *NDS Program Suite*

The Client commits to providing full access to its premises and the core business data required by UNODC to fulfil its obligations under the terms of this SLA.

In order to ensure a smooth operation of the system, the Client will provide full on-site and remote access for National Drug Control System - *NDS Program Suite* to designated UNODC personnel.

6. TERMINATION, REDUCTION OR SUSPENSION

- a) In the case of termination of this agreement, either party must notify the other of its intention to terminate the agreement three (3) months prior to the desired date of termination. In the event of such termination both parties shall agree to a mutually acceptable close-out and handover procedure.

- b) On expiration of this Agreement, the funds will continue to be held by UNODC until all expenditures it has incurred have been satisfied from such funds
- c) Any dispute which may arise between the parties as to the interpretation, application or performance of this Agreement, shall be dealt with in accordance with Clauses 7 of the SLA.

7. SETTLEMENT OF DISPUTES

7.1 Damages, Compensation and Allowance

The Client will have no claim for damages, compensation, allowance or otherwise by reason of, or directly or indirectly arising out of, any action taken or notice given by UNODC under the terms of this SLA except as expressly provided for herein.

7.2 Amicable Settlement

The Parties shall use their best efforts to amicably settle any dispute, controversy or claim arising out of, or relating to this SLA or the breach, termination or invalidity thereof.

Where the Parties wish to seek such an amicable settlement through conciliation, the conciliation shall take place in accordance with the then prevailing UNCITRAL Conciliation Rules, or in accordance to another procedure as may be agreed between the Parties.

7.3 Arbitration

Unless any such dispute, controversy or claim between the Parties arising out of or relating to this SLA, or the breach, termination or invalidity thereof is settled amicably under the preceding paragraph of this Section within sixty (60) days after receipt by one Party of the other Party's request for such amicable settlement, such dispute, controversy or claim shall be referred by either Party to arbitration in accordance with the UNCITRAL Arbitration Rules then prevailing.

The arbitral tribunal shall have no authority to award punitive damages. The Parties shall be bound by any arbitration award rendered as a result of such arbitration as the final adjudication of any such controversy, claim or dispute.

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8. GENERAL TERMS AND CONDITIONS

8.1 Intellectual Property Rights

The National Drug Control System - NDS Program Suite system is the property of The United Nations. The Client shall not alter, copy, distribute or share National Drug Control System - NDS Program Suite with any other party.

8.2 Discontinuation of Service

If for any reason, currently unforeseen, UNODC is unwilling or unable to support the National Drug Control System - NDS Program Suite application under this SLA, UNODC will provide on an "as is" basis to the Client, exclusively for its internal use and at no charge, all software source codes, application designs, schematics and documentation necessary to maintain and support the National Drug Control System - NDS Program Suite application.

8.3 Non-Disclosure Agreement

UNODC guarantees that it will hold in the strictest confidence and will not disclose any data of the Client that UNODC gains access to during the installation and maintenance of the National Drug Control System - NDS Program Suite.

The Client guarantees that no information about the National Drug Control System - NDS Program Suite system will be disclosed to an unauthorized third party.

8.4 Privileges and Immunities

Nothing in or relating to this SLA shall be deemed a waiver of any of the privileges and immunities of the United Nations of which UNODC is an integral part.

8.5 Liability as to Costs

UNODC shall not be liable for any costs beyond the amount set out in section 4.2 Payment Schedule of this agreement. Should the costs of the supply of services exceed the amount set out in the Agreement due to the actions or requests of the Client that fall outside of the maintenance services under the SLA, the following terms will apply:

- a) UNODC shall commence and continue to conduct operations under this agreement on the receipt of funds in accordance with the schedule of payments set out in section 4.2 *Payment Schedule* of this agreement.





- b) UNODC will not make any commitments above the amounts specified for expenditure in section 4.2 *Payment Schedule* of this Agreement.
- c) If the need for unforeseen expenditures arises, UNODC will submit a supplementary budget to the Client, outlining the additional funds for NDS *Program Suite* that will be necessary. If no additional funds for the NDS Program Suite are made available, the assistance provided to the Client under this Agreement may be reduced or, if necessary, terminated by UNODC. In no event, will UNODC assume any liability in excess of the funds for the NDS Program Suite provided.

8.6 Licenses

The National Drug Control System - NDS PROGRAM SUITE system is licensed for use and configuration as part of this SLA, to the Client.

Any additional third party licenses that are required to operate the National Drug Control System - NDS PROGRAM SUITE are not part of this SLA and must be acquired separately by the Client.

9. MISCELLANEOUS

9.1 Amendments

Any changes to the conditions of this Agreement require the written and signed consent of both parties. Any such letter of consent parties would form an integral part of this Agreement.

9.2 Entry into Force

The Agreement will enter into force on the date of the last signature by the authorized representatives of the Parties.

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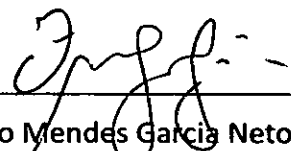
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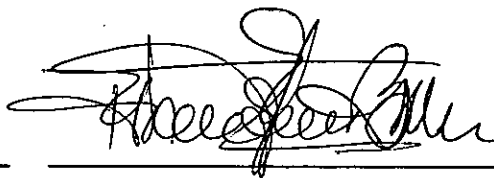
IN WITNESS WHEREOF, the Parties here to have signed this Agreement for the provision of services as specified herein:

For the
Brazilian Health Regulatory Agency
ANVISA

For the
United Nations Office on Drugs and Crime
UNODC



Fernando Mendes Garcia Neto
Acting Director President
Brazilian Health Regulatory Agency
ANVISA



Rafael Franzini Batlle
The United Nations Office on Drugs and
Crime
UNODC

Date: 03/08/2018

Date: 03/08/2018

Place: Brasília

Place: Brasília