National Guidelines on Estimation of Psychotropic Substances and Precursors

National Agency for Food and Drug Administration and Control, Nigeria

2017

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NATIONAL GUIDELINES ON ESTIMATION OF PSYCHOTROPIC SUBSTANCES AND PRECURSORS

National Agency for Food and Drug Administration and Control

Abuja, 2017

FOREWORD

I am indeed very pleased to write the foreword for this first edition of the **National Guidelines for the Estimation of Psychotropic Substances and Precursors (Guidelines)**. I am aware that the development of these guidelines began in 2014 and involved contributions and recommendations of stakeholders in various sectors. The availability of the right quality medicines is an essential step towards achieving the mission of NAFDAC - safeguarding the health of the nation as well as attaining Goal 3 of the Sustainable Development Goals – Good health and wellbeing.

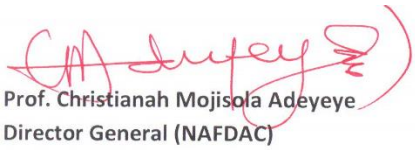
Psychotropic Substances and Precursors are essential for the treatment of a wide range of health conditions, and also have an important place in research. However, these products have a high abuse potential. In addition, they could be diverted for use to illicit drug manufacture.

The guidelines outline the steps and processes for various stakeholders to ensure that Nigeria has a realistic assessment of its needs for these very important products. Consequently, it is an essential tool for ensuring that these products are available for medical, scientific and industrial use while limiting their diversion to illicit use and abuse. This is because only countries that have an accurate needs estimate for controlled substances can put the measures in place to ensure adequate access and control.

It is instructive to note that the development of these guidelines involved the establishment of a Technical Working Group made up of key stakeholders and interest groups, to ensure wide consultations, and the resulting document reflects this input. The deployment of this guideline will ensure that information on national requirements for psychotropic substances and precursors is gathered and congregated in a way that will enable accurate submissions to the International Narcotics Control Board.

I commend all those who worked tirelessly towards the development of this guideline. Special mention and gratitude must go to the European Union for funding the NGAV16 project – Response to Drugs and Related Organized Crime in Nigeria, under which auspices these guidelines were developed as well as the United Nations Office on Drugs and Crime who are implementing the project.

Finally, let me stress that these guidelines must be widely circulated and disseminated. Everything possible must be done to ensure that health workers at all levels effectively utilize the guidelines to maximize the benefits to Nigeria. In addition, it must be subjected to periodic review to ensure continued relevance.



Prof. Christianah Mojisola Adeyeye
Director General (NAFDAC)

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The Guidelines were developed with the combined efforts, time, passion and technical expertise of members of the Technical Working Group on Control of Psychotropic Substances and Precursors in addition to other stakeholders.

Our deep appreciation goes to staff of health institutions and pharmacies that devoted time to the piloting of these guidelines in addition to their regular work schedules.

It is our hope that all stakeholders use the Guidelines to ensure improved access to and control of psychotropic substances and precursors in Nigeria.

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ACRONYMS

ACPN	Association of Community Pharmacists of Nigeria
ACS	American Cancer Society
COMHPFHI	Committee of Heads of Pharmacy in Federal Health Institutions
DPS	Director of Pharmaceutical Services
FMOH	Federal Ministry of Health
FORM A/P	Tool developed by the INCB and used by Member States to give quarterly statistical return data of import and exports of substances listed in Schedule II of 1971 Convention on Psychotropic Substances.
FORM B/P	Tool developed by the INCB and used by Member States to give annual statistical estimates of import and exports of substances listed in Schedule II, III and IV of the 1971 Convention on Psychotropic Substances.
FORM D	Annual information on Substances Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances listed in Tables I and II of Convention 1988.
HOD	Head of Department
INCB	International Narcotics Control Board
LMCU	Logistic Management Coordinating Unit
NAFDAC	National Agency for Food and Drug Administration and Control
NDLEA	National Drug Law Enforcement Agency
PCN	Pharmacists Council of Nigeria
SMOH	State Ministry of Health
TWG	Technical Working Group
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

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EXECUTIVE SUMMARY

Psychotropic substances and precursor are among the controlled drugs regulated by the international drug control conventions: the single convention on narcotic drugs of 1961, amended by the 1972 protocol; the convention on psychotropic substances of 1971; and the United Nations convention against illicit traffic in narcotic drugs and psychotropic substances of 1988. These conventions regulate and assure the availability of medicinal opioids, psychotropic substances, and precursors for medicinal and scientific use whiles stifling their diversion for illicit purposes. Psychotropic substances and precursors have a wide range of uses including adjuvants in pain management including treatment of neuropathic pain and in the management of obstetric emergencies including hemorrhage thus critical in reducing maternal deaths.

However, these drugs are also prone to abuse and illicit use and sometimes associated with crime. In a bid to control its misuse, its availability for therapeutic and scientific purposes could be compromised. The delicate balance between control against illicit use and providing for medical and scientific purposes needs careful attention with the right quantities needed for the later so as not to have excess in the system with potential for diversion.

Whiles mindful of the aforementioned and noting that baseline data is non-existent in Nigeria to inform evidence-based procurement of psychotropic substances and precursors to meet disease conditions needing them, this guideline has been developed to facilitate the process of estimating the actual quantities of psychotropic substances and precursors required for medicinal and scientific use.

The overarching aim of this national guideline on the estimation of psychotropic substances and precursors is to standardize the quantification practices in Nigeria and to assure evidence-based estimates of these drugs for medical and scientific use to the INCB.

1. BACKGROUND

There is a real need for the design and implementation of guidelines for estimating psychotropic substances and precursors in Nigeria to enable the country to have a more informed picture of her medical, industrial and scientific needs. The use of psychotropic substances and precursors have two different potentials: the potential to be used for licit purposes (medical, scientific and industrial) and to be diverted to illicit channels for trafficking and abuse which jeopardize the well-being of populations.

The international drug control system aims to ensure the availability of psychotropic substances and precursors for licit purposes while preventing diversion, abuse, and trafficking. The problem of inappropriate levels of consumption (too high in some countries and too low in others) has been a source of concern to the International Narcotics Control Board (INCB) for many years. The INCB and the World Health Organization (WHO) have made available general guidelines that countries can use as a guide in designing their own policies, taking into account the respective country's context, in order to ensure psychotropic substances and precursors are available for medical purposes while minimizing illicit use. The development of national estimation guidelines for psychotropic substances and precursors affirms this commitment by Nigeria. The international drug control regime that regulates the availability of controlled drugs for medicinal and scientific purposes whiles preventing diversion for illicit use is based on three (3) international conventions:

i. The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol,
ii. The Convention on Psychotropic Substances of 1971,
iii. The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988.

The 1961 Convention as amended and the 1971 Convention established control measures for narcotic drugs and psychotropic substances, whereas the 1988 Convention established control measures for precursors used in the illicit manufacture of narcotic drugs and psychotropic substances. As parties to these conventions, States accept the obligation to implement the provisions of the conventions in their national legislation.

The Federal Government of Nigeria has created two important institutions for the management of the controlled substances in question. These two institutions are the National Drug Law Enforcement Agency (NDLEA) and the National Agency for Food and Drug Administration and Control (NAFDAC) working to ensure availability of these drugs for licit use while preventing diversion to illicit use and abuse.

The European Union funded and UNODC implemented project, "*Response to Drugs and Related Organized Crime in Nigeria*" (2013-2019), which aims to support Nigeria's efforts in fighting illicit drug production, trafficking and use, and in curbing related organized crime,is also focused on supporting the Federal Ministry of Health (FMOH) and NAFDAC for improved estimation, control and availability of psychotropic substances and precursors for medical, industrial and scientific purposes.

The first necessary step to estimate the country's actual requirement for psychotropic substances and precursors is the elaboration of national estimation guidelines. Countries that are in a position to adequately assess their requirements for psychotropic substances and precursors are typically the ones that are able to take the steps required to improve availability. The ultimate aim of the national estimation guidelines is to significantly improve the existing estimation practices in Nigeria to ensure availability of psychotropic substances and precursors for licit use as well as to contribute to a more accurate worldwide estimation by INCB.

2. CHRONOLOGY IN THE DEVELOPMENT OF THE NATIONAL ESTIMATION GUIDELINES

The development of the national estimation guidelines started in September 2014 as part of the UNODC implemented project. There were many stakeholder consultations including the Technical Working Group, culminating in this final document. The trajectory of its development is detailed in Annex 1.

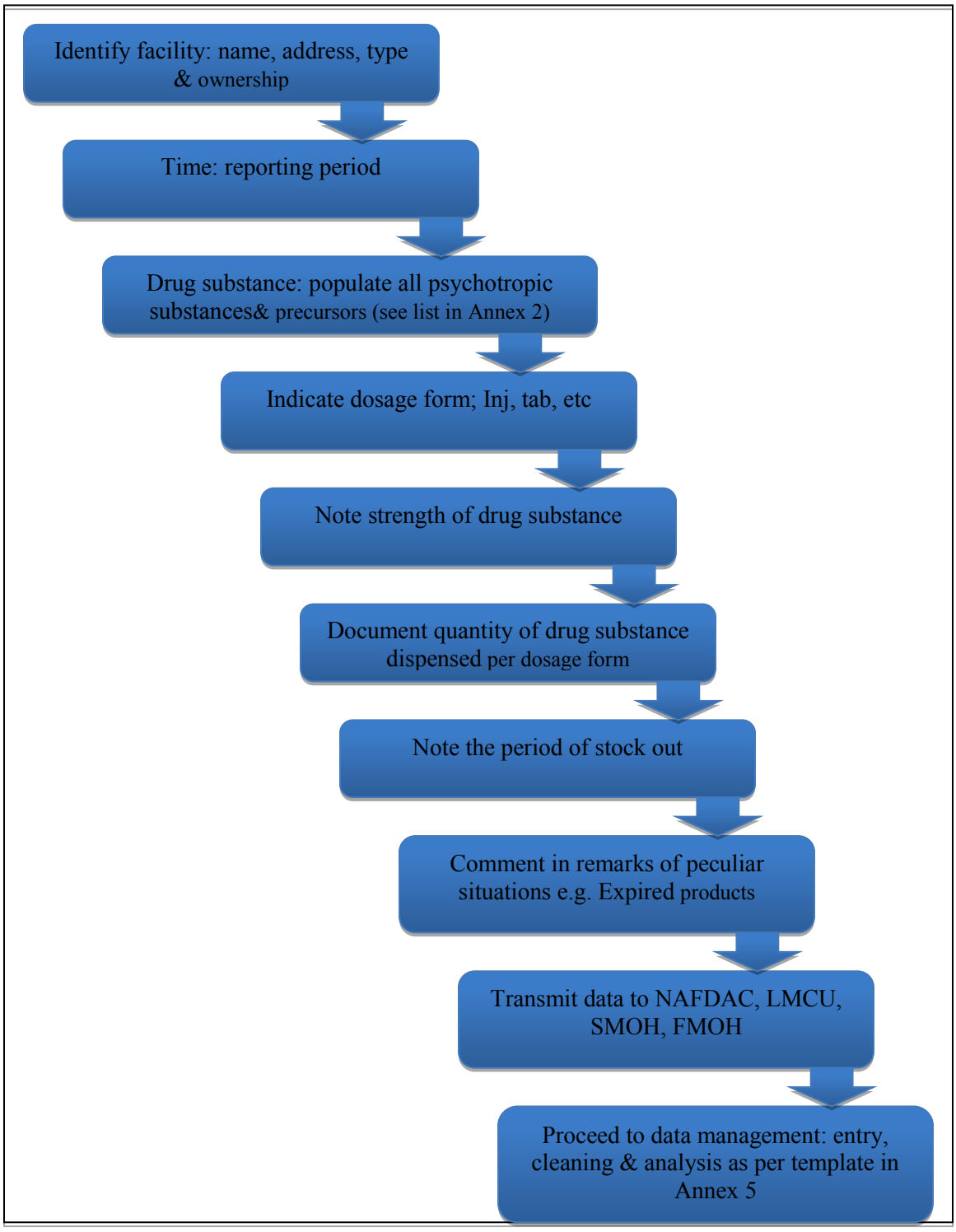
3. GOAL:

To establish an estimation practice in the country that will ensure that psychotropic substances and precursors are principally available for licit use.

4. OBJECTIVES:

- To estimate the national need for psychotropic substances and precursors for licit uses.
- To provide realistic annual estimates to INCB.

5: THE GUIDELINE



The flow chart above demonstrates the sequence of data identification, collection, transmission and management. Data collection is facilitated using the tools, Form EP 01 (*for health facilities*) and Form EP 02 (*for community pharmacies*) shown in Annexes 3a and 3b.

The tool requires the identification of facilities contributing data with full address, type of facility and ownership (private or public). The reporting period must be indicated; e.g. January 1, 2016 to December 31, 2016. Relevant psychotropic substances and precursors that were stocked and or dispensed during the reporting period are populated under the drug substance (*see Annex 3*). The formulations are similarly documented on the data collection tool.

The dosage form (*injection, syrup, tablet, etc.*) of each drug substance is as well indicated. Subsequently, the strength of corresponding drug substances is indicated. Particular attention must be given to injections, syrups, and suspensions. These must be entered thus 5mg/1ml in 2ml ampoule, 2mg/1ml in 50ml vial, 5mg/5ml in 100ml bottle, etc. The total strength per the ampoule, vial or bottle can then be appropriately derived to conclude the drug substance characteristics.

The quantity of the drug substance dispensed per each dosage form during the year under review is captured in the data collection tool. This takes the form, number of tablets, capsules, ampoules, vials, bottles, etc. It is assumed in this circumstance that all dispensed medications are fully consumed. The quantity dispensed per drug substance (*physical count*) and strength (*mcg, mg, etc.*) subsequently translates into the "quantity dispensed in mg" for the year under review. The data entry template (*Annex 5*) auto-computes this and subsequent strengths in grams and kilograms.

It is important to note the period of stock out to assist in computing the average daily consumption extrapolated to annual consumption. Important observations should be documented in the remarks column.

The collated data should be forwarded to the LMCU for entry into the data entry template and subsequently transmitted to NAFDAC and FMOH for further analysis as shown in the narrative following.

6. THE ESTIMATION GUIDELINES

The estimation of psychotropic substances and precursors can be established through routine data returns from health–care facilities, pharmacies, veterinary institutions, manufacturers, importers and exporters among others. This is complemented through scheduled field surveys, which could also provide baseline information.

In conducting field surveys for psychotropic substances and precursors, facilities of interest are selected using the appropriate statistical method to enhance the accuracy, reliability, replicability, authenticity and extrapolation of results. There are three widely used methods in estimating for controlled substances as follows:

i. Consumption-based methods and variants,
ii. Morbidity-based method, and
iii. Service-based method.

This guideline focuses on the consumption – based method.

6.1 Selection and data collection for medical use at health care facilities level

Selection of health facilities in a survey for psychotropic substances and precursors may follow a multi – cluster sampling method to adequately represent all geopolitical zones and health facility type including primary, secondary and tertiary institutions as per classification by the Federal Ministry of Health.

The drug substances of interest in the category of psychotropic substances and precursors are then populated by reviewing appropriate hospital records like patient folders, drug ledgers in the pharmacy and bin/tally cards among others. Alternatively, similar information may be obtained through qualitative survey including Focused Group Discussion (FGD) and In-depth Interviews of Key Informants (KII).A list of psychotropic substances and precursors surveyed in Nigeria is populated in Annex 2.

The quantities of these drugs are then estimated using any of the aforementioned methods. The required quantities for a year should be determined in the month of January of the preceding year.

6.1.1: Consumption-based method

This approach and its variants are based on use of psychotropic substances and precursors over recent years. If past use of these drugs is stable and adequate, future requirements can be calculated by averaging the amounts used in health-care facilities in recent years and adding a margin for unforeseeable increases.

In variants of this method, calculations are based on data obtained from manufacturers, importers and wholesalers that distribute the psychotropic substances and precursors to the end users through an established supply chain like the Federal Medical Stores to the State Medical Stores and to the health facilities.

This method is appropriate in the following situations, which may not have been perfect in the Nigerian case:

a. When reliable data on past use can be collected;
b. Where the demand for health-care services has reached a relatively steady level;
c. When the demands of the health-care system are met by an established and functional supply management system that ensures an uninterrupted supply of psychotropic substances and precursors; and
d. When the use of these controlled substances is rational.

Caution may be exercised when using the consumption-based method and variants in the following situations:

a. The method does not necessarily improve rational prescribing;
b. In situations of consumption-based variants, calculations centered on quantities requested by trading companies for future sales may be influenced by market dynamics and thus not reflect medical requirements;
c. Long periods of stock out, loss and wastage may reduce the accuracy of the method. Thus, in situations of stock out, computation of average daily consumption is encouraged and this is extrapolated over 365 days for the average annual consumption; and
d. Data collected under this method may be incomplete because of poor stock management, inadequate record keeping or inadequate reporting to the authorities responsible for data collection. Hence it is advisable to collect data over a period of not less than 3 years, across several facility types and a rather high sample size to reduce the impact of the aforementioned.

The detail of this method is described in **Annex 4**and the data collection tool (**EP 01**) is demonstrated in **Annex 3a.** Meanwhile in routine data collation, the following may apply:

a. In December of the previous year, the Director of Pharmaceutical Services (DPS) request health facilities in the states to submit annual consumption by January using the standard appropriate forms --- INCB/NAFDAC,
b. These returns are collated and an overage of 10 percent is added to take care of unforeseeable requirements. The collated data is forwarded to the Director of Narcotics and Controlled Substances (NAFDAC) before the end of March, and
c. The annual consumption estimated for the year established and transmitted to the INCB using the standard prescribed forms.

6.2: Selection and data collection by pharmacies and veterinary clinics

Employing the appropriate statistical method and applying the consumption-based method, data from selected facilities is collected using the appropriate data collecting tool, EP 01 in Annex 3a for veterinary facilities and EP 02 in Annex 3b for community pharmacies. These data are analyzed and the estimates transmitted to the appropriate authorities (NAFDAC, LMCU, SMOH & FMOH) for utilization. A sample of the data entry template is shown in Annex 5 and display of expected results with 10% mark up in MS Excel is also demonstrated in Annex 6.

6.3: Selection and data collection for scientific purposes

Institutions engaged in forensic analysis, teaching and research may estimate the quantity of psychotropic substances and precursors they need for the year and send requests to the Director, Narcotics and Controlled Substances of NAFDAC by end of March using the prescribed form. A collation of these quantities and returns for the previous year will provide an idea of the actual need of these institutions in the country and be factored into the general country

estimates. Scheduled surveys may be used to complement data from the routine method using the validated form EP 01in Annex 3a.

6.4: Selection and data collection by manufacturers, exporters, and importers

- Manufacturers, exporters and importers registered with NAFDAC are populated and followed through with their request and returns on psychotropic substances and precursors. This list may be linked to other facilities not registered with the competent authorities through snow balling and data requested from them as well using the prescribed forms.
- Manufacturers, importers and exporters should send to the Directorate of Narcotics and Controlled Substances NAFDAC, requests for quantities of psychotropic substances and precursors they need to manufacture; import; and export using the prescribed form by end of March each year.
- Manufacturers should consider the stocks of psychotropic substances and precursors to be held as at 31 December of the year to which the estimate relates. These stocks refer to the quantities of psychotropic substances and precursors to be held in reserve by manufacturers at the end of the year. As a general rule, they should not exceed the requirements for psychotropic substances and precursors calculated for 1 year. Stocks must be adequate to provide a safeguard to any shortage in supply, for example as a result of delays in delivery.
- They should indicate the quantities used in their preparations, the quantities manufactured, and the distribution records of the product.
- They should provide the quantities exported during the previous year and estimate quantities to be exported the next year.
- They must also provide the amount of psychotropic substances and precursors they will need as reserve stocks.

The steps outlined above support data gathering through the routine means and could as well provide relevant information for scheduled surveys using the validated forms EP 01 & EP 02 in Annexes 3a &3b. The survey tools for manufacturers, importers and exporters is also posted in Annex 7.

7. ESTIMATION AND DATA ANALYSIS

7.1: Guidance for estimation

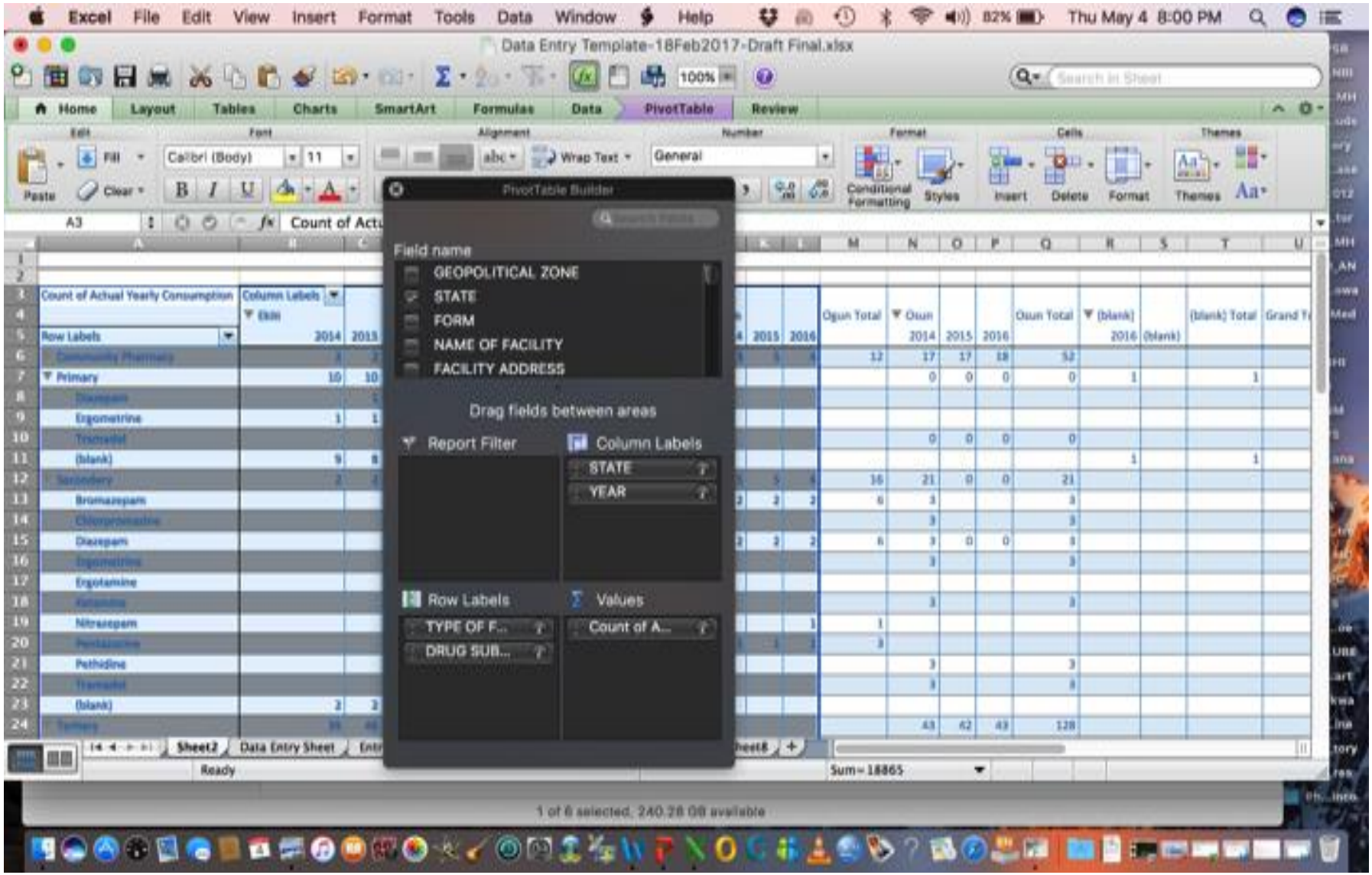
- Attention should be paid to estimates of schedules II, III and IV psychotropic substances and precursors submitted by researchers, importers and manufacturers.
- Estimates of excessively high quantities should be avoided to prevent overstocking/stock piling, which might lead to diversion.
- On the other hand, underestimation should be avoided to ensure availability and accessibility of psychotropic substances and Precursors for medical and scientific use

7.2: Methodology for estimation

- Collate the overall quantity requested for each psychotropic substance and precursor using the appropriate forms from DPSs, Health facilities /treatment centers, researchers, importers, exporters and manufacturers.
- Analyze the data for different substances and identify various trends, and consumption patterns.
- Profile treatment centers, research entities, importers, and manufacturers, distribution chains to establish the capacity to utilize.
- Where morbidity data exists, use it to refine the available consumption data. This analysis should also take into account shifts in population.

7.3: Data analysis

Analysis is facilitated by the data entry and analytic template shown in Annex 5 and the Pivot Table in MS Excel as shown below.


Excel File Edit View Insert Format Tools Data Window Help
Data Entry Template-18Feb2017-Draft Final.xlsx
Home Layout Tables Charts SmartArt Formulas Data PivotTable Review
PivotTable Builder
Field name
GEOPOLITICAL ZONE
STATE
FORM
NAME OF FACILITY
FACILITY ADDRESS
Drag fields between areas
Report Filter
Column Labels
STATE
YEAR
Row Labels
Values
TYPE OF F...
DRUG SUB...
Count of A...
Count of Actual Yearly Consumption
Row Labels
Sheet2
Data Entry Sheet
Ready
Sum=18865

The output form for the estimated quantities of psychotropic substances and precursors by year is also demonstrated in Annex 5. Details of the output forms (varied) may be found in the survey report available on request from the UNODC project office, Nigeria.

8. FORMS FOR DATA COLLECTION

The EU funded and UNODC implemented project on "*Response to Drugs and Related Organized Crime in Nigeria*" have developed and validated forms EP 01 and EP 02 (**Annexes 3a &3b**) for data collection from health facilities and community pharmacies. These could also be used in collecting data from other institutions using controlled drugs.

9. MONITORING THE ESTIMATION PROCESS

This should be a shared responsibility of FMOH and NAFDAC. These competent authorities must encourage all institutions under their purview to keep good records to facilitate easy retrieval, analysis and transmission of data informing relevant national estimates of psychotropic substances and precursors.

- NAFDAC must maintain Good Record Management Practices and document all its activities (e.g. issuance of permits or inspection of facilities) as the records would strengthen the estimation exercise.
- NAFDAC should encourage stakeholders at all levels of the system to maintain electronic versions of their data.
- NAFDAC should regularly evaluate the effectiveness of the estimation process and of the accuracy of the calculated requirements by reconciling with the baseline data of estimated controlled substances by geopolitical zone, state and facility type. Assess the effectiveness with which the various steps of the process (example: data collection) have been carried out. Problems at each step should be identified and corresponding solutions introduced.
- On regular scheduled basis (bi-annually), surveys for psychotropic substances and precursors may be carried out to compare with data collated from routine process for deviations. Any major discrepancy is corrected to reflect the true country estimate.

10. SUBMISSION OF NATIONAL ESTIMATES OF PSYCHOTROPIC SUBSTANCES AND PRECURSORS

The administration of the system of estimates and assessments for psychotropic substances and precursors are summarized in Annex 8.

10.1: Psychotropic substances[1]:

- The INCB provides all Governments, in the first quarter of each year, with form B/P (Assessment of annual medical and scientific requirements for substances in Schedules II, III and IV of the Convention on Psychotropic Substances of 1971).

Governments may submit revisions of the assessments at any time, using form B/P.

- Assessments are examined by INCB and explanations are requested, if required. The assessments for psychotropic substances for all countries are published annually by INCB in the technical report on assessments of annual medical and scientific requirements for substances in Schedules II, III and IV of the Convention on Psychotropic Substances of 1971. In addition, the amended assessments are published on the INCB website on a monthly basis and are sent to Governments in a supplement to the technical report that is published on a quarterly basis.

10.2: Precursors[1]:

- The following are among precursors of interest to the INCB: ephedrine, pseudoephedrine, 3,4-methylenedioxyphenyl-2-propanone and 1-phenyl- 2-propanone. To assist countries and territories in submitting estimated requirements for, the INCB provides all Governments, in the first quarter of each year, with form D (Annual information on substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances). Form D should be submitted to INCB by **30 June** of the year preceding that to which the estimates relate (for example, estimates of requirements for 2013 should be submitted in form D by 30 June 2012). Governments may submit revisions of the estimates at any time.
- Confirmation by INCB of estimated requirements furnished by Governments is not required. The estimated requirements for the four precursors of amphetamine-type stimulants as furnished by Governments are published annually by INCB in the report on precursors and chemicals frequently used in the illicit manufacture of narcotic drugs and psychotropic substances. In addition, the estimates are published and updated on the INCB website on a regular basis (see www.incb.org/ incb/precursor_estimates.html).

11. COORDINATION OF THE ESTIMATION PROCESS

NAFDAC and FMOH shall complement each other in the management of psychotropic substances and precursors. It is absolutely essential for them to coordinate activities in the management and monitoring of these drugs.

- NAFDAC shall coordinate the entire process for the estimation of psychotropic substances and precursors in Nigeria. This should apply to routine data management.
- The FMOH must support NAFDAC to carry out scheduled surveys on psychotropic substances and precursors to complement routine data returns and observe for any variance.
- NAFDAC and the FMOH must organize training and educational activities for all stakeholders in relation to adequate record management for the estimation process

[1]INCB & WHO (2012). Guide on Estimating Requirements for Substances under International Control

with regards to psychotropic substances and precursors. This process must be a joint activity.

12. ADDITIONAL ACTIONS REQUIRED

- This Guideline should be reviewed every three (3) years by NAFDAC and the FMOH.
- NAFDAC and the FMOH should assist DPSs, Health facilities /treatment centers, scientists, researchers, manufacturers, importers and exporters with their responsibility in providing the relevant data for the national estimates.
- NAFDAC and the FMOH should ensure that, stakeholders designate staff for the management of records in support of the estimation process.
- NAFDAC personnel and FMOH staff (especially records management and IT staff) should be trained in the use of the consumption-based method of estimation in the present situation. Training of Trainers (ToT) modules (training manual)should be developed to facilitate scaling up training.
- Using ToT trained personnel, NAFDAC and FMOH should provide training to designated stakeholders with regards to data collection and management processes.
- Feedback on data transmitted should be provided to institutions and personnel providing these data – positive reinforcement.

Annex 1: Chronology in the development of the national estimation guidelines

i. In September 2014, as part of the UNODC implemented project, a review and analysis of international, regional and national guidelines on estimation was undertaken by a consultant engaged by the project. This included a review of best practices and international recommendations from INCB and other organizations; as well as policies, work plans and guidelines from Nigeria.

ii. In October 2014, due consultations were held through meetings and a workshop with the members of the Technical Working Group on control of narcotics, psychotropic substances and precursors for medical, industrial and scientific use in Nigeria were held in collaboration with NAFDAC and UNODC in order to gather information and understand the priorities of the government and stakeholders in the Nigerian context

iii. In November 2014, a second consultant developed the draft guidelines, which was adapted for implementation in the Nigerian context based on the above information and analysis.

iv. In February 2015, the draft guidelines were reviewed and revised at a workshop by the members of the TWG on control of narcotics, psychotropic substances and precursors in Nigeria.

v. The estimation tools were field tested at selected health facilities in the country

vi. The Technical Working Group (TWG) validated the field-tested estimation tools for inclusion in the Guidelines.

vii. In October, 2016, the draft Guidelines were piloted in selected States in the 6-geopolitical zones of the country namely Gombe, Kano, Oyo, Kwara, Enugu and Edo states to determine its practicability.

viii. In November 2016, the pilot of the quantification and estimation exercises' result was reviewed.

ix. In March-April 2017, the quantification and estimation exercise were scaled up to include the 36 states & FCT. Also, data collection, analysis and realistic estimates were established.

x. In August 2017, The Guidelines for Estimation of Psychotropic Substances and Precursors was finalized by TWG.

xi. The final draft of the Guidelines for Estimation of Psychotropic Substances and Precursors was presented to NAFDAC Governing Council.

xii. The Guidelines for Estimation of Psychotropic Substances and Precursors was published and disseminated.

Annex 2: List of psychotropic substances and precursors

Psychotropic Substances …	*… Psychotropic Substances*	*Precursors*
Amitriptyline Tablet 25mg	Pentobarbitone Injection 200mg/ml in 1ml	Ephedrine Injection 30mg/ml in 1ml
Amitriptyline Tablet 50mg	Pentobarbitone Syrup 15mg/5ml in 100ml	Ephedrine Syrup 3mg/5ml in 100ml
Bromazepam Tablet 1.5mg	Pentobarbitone Syrup 15mg/5ml in 60ml	Ephedrine Syrup 6mg/5ml in 100ml
Bromazepam Tablet 3mg	Pentobarbitone Tablet 200mg	Ephedrine Syrup 7.2mg/5ml in 100ml
Clomipramine Tablet 25mg	Pentobarbitone Tablet 30mg	Ephedrine Tablet 11mg
Clomipramine Tablet 75mg	Pentobarbitone Tablet 60mg	Ephedrine Tablet 16mg
Clonazepam Tablet 2mg	Phenobarbitone Injection 100mg/ml in 1ml	Ephedrine Tablet 25mg
Diazepam Injection 10mg/2ml in 2ml	Phenobarbitone Injection 100mg/ml in 2ml	Ephedrine Tablet 30mg
Diazepam Injection 5mg/ml in 2ml	Phenobarbitone Injection 15mg/ml in 2ml	Ephedrine Tablet 5mg
Diazepam Tablet 10mg	Phenobarbitone Injection 200mg/ml in 1ml	Ergometrine Injection 0.5mg/2ml in 2ml
Diazepam Tablet 5mg	Phenobarbitone Syrup 15mg/5ml in 100ml	Ergometrine Injection 0.2mg/ml in 1ml
Flunitrazepam Tablet 1mg	Phenobarbitone Syrup 15mg/5ml in 60ml	Ergometrine Injection 0.5mg/ml in 1ml
Ketamine Injection 10mg/ml in 20ml	Phenobarbitone Tablet 100mg	Ergometrine Injection 0.5mg/ml in 2ml
Ketamine Injection 50mg/ml in 10ml	Phenobarbitone Tablet 15mg	Ergometrine Tablet 0.5mg
Ketamine Injection 50mg/ml in 1ml	Phenobarbitone Tablet 30mg	Ergometrine Tablet 1mg
Lorazepam Tablet 1mg	Phenobarbitone Tablet 60mg	Ergotamine Injection 0.5mg/ml in 1ml
Lorazepam Tablet 2mg	Thiopentone Injection 1000mg/10ml in 10ml	Ergotamine Injection 0.5mg/ml in 2ml
Lorazepam Tablet 3mg	Thiopentone Injection 500mg/10ml in 10ml	Ergotamine Tablet 0.5mg
Methylphenidate Tablet 10mg	Thioridazine Tablet 100mg	Ergotamine Tablet 1mg
Methylphenidate Tablet 18mg	Thioridazine Tablet 50mg	Ergotamine Tablet 2mg
Methylphenidate Tablet 36mg		Pseudoephedrine Syrup 15mg/5ml in 100ml
Midazolam Injection 5mg/ml in 1ml		Pseudoephedrine Syrup 15mg/5ml in 50ml

Midazolam Injection 5mg/ml in 3ml		Pseudoephedrine Syrup 30mg/5ml in 100ml
Nitrazepam Tablet 10mg		Pseudoephedrine Syrup 30mg/5ml in 50ml
Nitrazepam Tablet 5mg		Pseudoephedrine Syrup 30mg/5ml in 60ml
Pentazocine Injection 15mg/ml in 2ml		Pseudoephedrine Syrup 6mg/ml in 100ml
Pentazocine Injection 30mg/ml in 1ml		Pseudoephedrine Syrup 9.38mg/ml in 15ml
Pentazocine Tablet 30mg		Pseudoephedrine Tablet 30mg
Pentazocine Tablet 50mg		Pseudoephedrine Tablet 5mg
Pentobarbitone Injection 100mg/ml in 1ml		Pseudoephedrine Tablet 60mg

Annex 3a: Data collection tool for the estimation of psychotropic substances and precursors in health facilities

Form EP 01: Estimation of Psychotropic Substances and Precursors in Health Facilities using consumption-based approach (*This should be completed at the end of the year being reported on*).

NAME OF FACILITY:								
ADDRESS:								
TYPE OF FACILITY (PRIMARY, SECONDARY, TERTIARY):						**OWNERSHIP (PRIVATE, PUBLIC, ETC)**		
YEAR (2014, 2015 & 2016):			**REPORTING PERIOD (e.g. Jan 1– Dec 31):**					
	DRUG SUBSTANCE INDICATED (see list below)	**DOSAGE FORM** e.g tab, inj	**STRENGTH** e.g mcg or mg (Indicate total volume of ampoule, vial, bottle, etc)	**QUANTITY** Dispensed for each dosage Form (No. of Tabs, Ampoules . .)	**QUANTITY** Dispensed for each Dosage Form in mcg or mg **Do not fill**	**TOTAL** Quantity of Drug Substance Indicated in grams **Do not fill**	**PERIOD of Stock Out** For Each Dosage Form in Days	**Remarks (eg how much expired, pilfering, etc)**
S/N	**(A)**	**(B)**	**(C)**	**(D)**	**E= C X D**	**F= E (mg) * 10^{-3}**	**(G)**	**(H)**
	Diazepam	Tab	10mg	500	5000	**5**	**0**	**Example**
1								
2								
3								
4								

	DRUG SUBSTANCE INDICATED (see list below)	**DOSAGE FORM** e.g. tab, inj	**STRENGTH** e.g. mcg or mg (Indicate total volume of ampoule, vial, bottle, etc.)	**QUANTITY** Dispensed for each dosage Form (No. of Tabs, Ampoules . .)	**QUANTITY** Dispensed for each Dosage Form in mcg or mg **Do not fill**	**TOTAL** Quantity of Drug Substance Indicated in grams **Do not fill**	**PERIOD of Stock Out** For Each Dosage Form in Days	**Remarks (eg how much expired, pilfering, etc)**
S/N	**(A)**	**(B)**	**(C)**	**(D)**	**E= C X D**	**F= E (mg) * 10^{-3}**	**(G)**	**(H)**
5								
6								
7								
8								
9								
10								

FOOT NOTE:

- [illegible] out columns E & F
- Column C should indicate the strength per tablet, ampoule, vial or entire bottle of syrup or suspension
- Column D will be obtained from Stock Card and by Physical Count

Form Completed by (name and position): Phone number:	**Submission Approved by** (name and position): Phone number:	**Date Form submitted:**

Any additional useful information gathered from the field:

- ***Drug substance*** (means pharmaceutical products containing psychotropic substances/precursors):
  - ✓ **Psychotropic substances**: *Benzodiazepines* (Diazepam, Flunitrazepam, Bromazepam, Chlordiazepoxide, Nitrazepam, Lorazepam, Alprazolam, Midazolam, Clonazepam); *Barbiturates* (Phenobarbitone, Pentobarbitone, Thiopentone); *Methylphenidate*; *Ketamine, Pentazocine*
  - ✓ **Precursors**: Pharmaceutical products containing *Ephedrine* and *Pseudoephedrine*; *Ergotamine*; *Ergometrine*

  This list is not exhaustive but simply a guide.

Key:
Drug substance: Include all the psychotropic substances and precursors used in the facility in the last 3 years as captured at the end of the checklist.
Dosage form: Documented as tablet, injection, syrup, etc.
Strength: Captured as mg or mcg per tablet or total mg/mcg per ampoule, vial or bottle specifying volume.
Quantity dispensed per dosage form: Describes the physical quantity of drug dispensed, eg ampoules/tablets.
Quantity dispensed for each dosage form in mcg or mg & Total quantity of drug substance indicated in grams: These are computed values and should not be filled.
Period of stock out in days: This is needed to compute the daily consumption and hence yearly consumption if missing values prevail.

Annex 3b: Form EP 02: **Data collection tool for the estimation of psychotropic substances and precursors in community pharmacies** (*This should be completed at the end of the year being reported on*).

Method: Consumption-based method and variants

NAME OF FACILITY:								
ADDRESS:								
OWNERSHIP (PRIVATE, PUBLIC, ETC):								
YEAR (2014, 2015 & 2016):			**REPORTING PERIOD (e.g. Jan 1– Dec 31):**					
	DRUG SUBSTANCE INDICATED (see list below)	**DOSAGE FORM** e.g. tab, inj	**STRENGTH** e.g. mcg or mg (Indicate total volume of ampoule, vial, bottle, etc.)	**QUANTITY** Dispensed for each dosage Form (No. of Tabs, Ampoules . .)	**QUANTITY** Dispensed for each Dosage Form in mg **Do not fill**	**TOTAL** Quantity of Drug Substance Indicated in grams **Do not fill**	**PERIOD of Stock Out** For Each Dosage Form in Days	**Remarks (e.g. how much expired, pilfering, etc.)**
S/N	**(A)**	**(B)**	**(C)**	**(D)**	**E= C X D**	**F= E (mg) * 10^{-3}**	**(G)**	**(H)**
	Ketamine	Inj	50mg/ml (10ml)	500	500mg * 500= **250,000**	**250mg**	**0**	**Example**
1								
2								
3								
4								
5								

	DRUG SUBSTANCE INDICATED (see list below)	**DOSAGE FORM** e.g. tab, inj	**STRENGTH** e.g. mcg or mg (Indicate total volume of ampoule, vial, bottle, etc.)	**QUANTITY** Dispensed for each dosage Form (No. of Tabs, Ampoules . .)	**QUANTITY** Dispensed for each Dosage Form in mg **Do not fill**	**TOTAL** Quantity of Drug Substance Indicated in grams **Do not fill**	**PERIOD of Stock Out** For Each Dosage Form in Days	**Remarks (e.g. how much expired, pilfering, etc.)**
S/N	**(A)**	**(B)**	**(C)**	**(D)**	**E= C X D**	**F= E (mg) * 10^{-3}**	**(G)**	**(H)**
6								
7								
8								
9								
10								
11								
12								

FOOT NOTE:	• [illegible] out columns E & F
	[illegible] Column C should indicate the strength per tablet, ampoule, vial or entire bottle of syrup or suspension
	[illegible] Column D will be obtained from Stock Card and by Physical Count

Form Completed by (name and position): Phone number:	**Submission Approved by** (name and position): Phone number:	**Date Form submitted:**

Any additional useful information gathered from the field:

- ***Drug substance*** (means pharmaceutical products containing psychotropic substances/precursors):
  - ✓ **Psychotropic substances**: *Benzodiazepines* (Diazepam, Flunitrazepam, Bromazepam, Chlordiazepoxide, Nitrazepam, Lorazepam, Alprazolam, Midazolam, Clonazepam); *Barbiturates* (Phenobarbitone, Pentobarbitone, Thiopentone); *Methylphenidate*; *Ketamine, Pentazocine*
  - ✓ **Precursors**: Pharmaceutical products containing *Ephedrine* and *Pseudoephedrine*; *Ergotamine*; *Ergometrine*

  This list is not exhaustive but simply a guide.

Key:
Drug substance: Include all the psychotropic substances and precursors used in the facility in the last 3 years as captured at the end of the checklist.
Dosage form: Documented as tablet, injection, syrup, etc.
Strength: Captured as mg or mcg per tablet or total mg/mcg per ampoule, vial or bottle specifying volume.
Quantity dispensed per dosage form: Describes the physical quantity of drug dispensed, e.g. ampoules/tablets.
Quantity dispensed for each dosage form in mcg or mg & Total quantity of drug substance indicated in grams: These are computed values and should not be filled.
Period of stock out in days: This is needed to compute the daily consumption and hence yearly consumption if missing values prevail.

Annex 4: Consumption-based methods and variants

The consumption-based method and its variants are necessarily based on past health-care demands for psychotropic substances and precursors. In situations where the past use of these drugs is stable, future requirements can be estimated by averaging the amounts consumed in recent years and adding a margin for unforeseeable increases. A variant of this method may also be applied when patterns of past use of controlled substances show a clear upward or downward trend and when known explanations for such trends allow for the prediction of future changes in use[1].

Data collection:

The following procedure should be followed in collecting data:

1: Identify the stakeholders in the psychotropic substances and precursors supply management system including manufacturers and importers and health-care system like health facilities (hospitals) and community pharmacies who handle these drugs.

2: Obtain the quantities of psychotropic substances and precursors used, requested and imported during the previous three years, as a minimum (see data collecting instrument (EP 01) in Annex 3a).

3: Identify new situations that require additional quantities of psychotropic substances and precursors (e.g. Pain Free Hospital Initiative – PFHI project, establishment of new Hospices and Palliative Care Centres, and population size changes).

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1 INCB & WHO (2012). Guide on Estimating Requirements for Substances under International Control

Calculation procedure:

Here is an **example** showing how to compute a country's Diazepam requirement:

Calculating the diazepam requirement for the treatment of anxiety, insomnia, status epilepticus, febrile convulsions, adjunct in acute alcohol withdrawal and muscle spasm in Nigeria for 2017.

Step 1: (a) Average the data (from step 2 of the data collection procedure) from the previous three years.

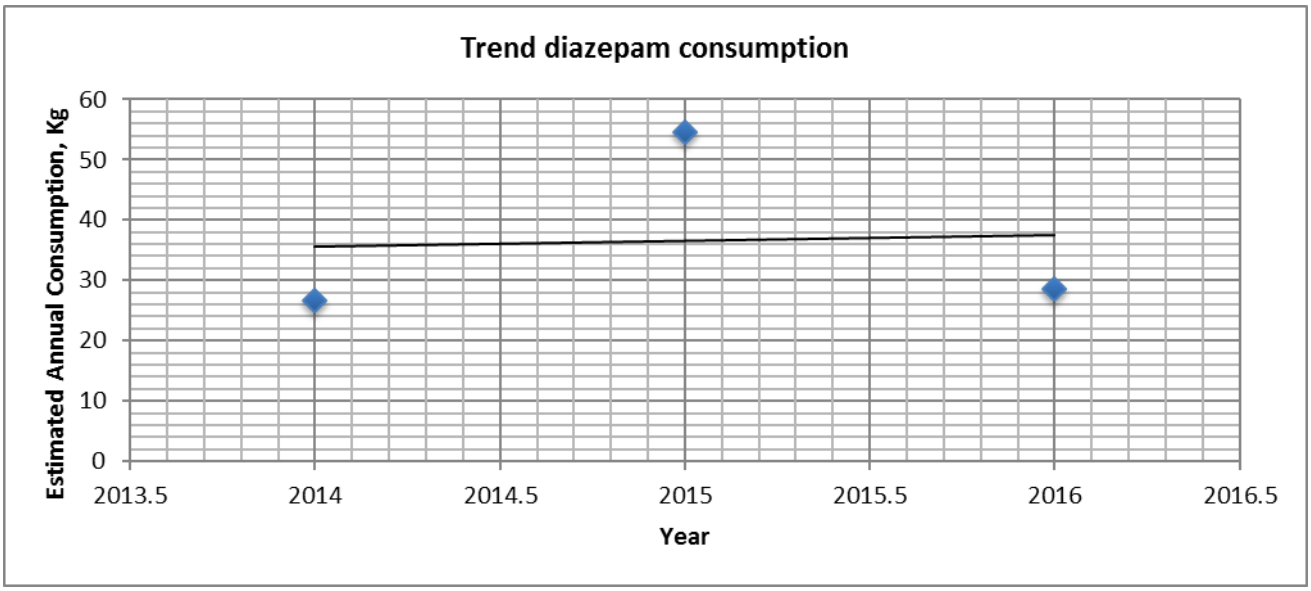
Records kept by the competent authorities indicate that diazepam use for the three-year period 2014-2016 was as follows:

Year	Diazepam consumption (Kg)
2014	338.7442
2015	236.6867
2016	166.893

The average for the period under study is calculated as follows: (338.7442kg + 236.6867kg + 166.893kg)/3 = **247.4413**Kg

(b) Increase the calculated average by 10 per cent to allow for unforeseeable circumstances, as follows: 247.4413 kg + 24.74413 kg = 272.18543Kg

Step 2: Add to the value of the result from step 1 (b) of the calculation procedure the additional quantities mandated by changes in circumstances (from step 3 of the data collection procedure described above).



Assume that the competent authorities have been informed that the new paediatric and neurological wards of the central hospital will require diazepam in different forms, including suppositories and injections, for the treatment of seizures of infants, children and epileptic patients, treatment of muscle spasm and peri-operative use. Based on past morbidity data (as shown in the figure above) of comparable paediatric and neurological hospitals, it is estimated that the new wards will require 5 kg of diazepam. Therefore, this quantity is added to the value of the result of step 1 (b), as follows:272.18543kg + 5 kg = **277.18543 kg**

This is the estimated diazepam requirement for the treatment of the above-mentioned conditions in Nigeria in 2017 [1].

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1 INCB & WHO (2012). Guide on Estimating Requirements for Substances under International Control

Annex 5: Example of partial data entry template showing calculation of actual yearly consumption

Drug Category	Drug Substances dosage form Strength	TOTAL STRENGTH IN FIGURES [e.g 100= 50mg/ml (2ml)]	QUANTITY DISPENSED FOR EACH DOSAGE FORM (No. of Tabs, Ampoules . .)	PERIOD OF STOCK OUT FOR EACH DOSAGE FORM IN DAYS	QUANTITY Dispensed for each Dosage Form in mg	TOTAL Quantity of Drug Substance Indicated in grams	# DAYS the drug was available	Actual Daily Consumption	Actual Yearly Consumption
Precursors	Ergometrine Injection 0.5mg/ml in 1ml	0.5	210	0	105	0.105	365	0.000287671	0.105
Precursors	Ergometrine Injection 0.5mg/ml in 1ml	0.5	187	0	93.5	0.0935	365	0.000256164	0.094
Precursors	Ergometrine Injection 0.5mg/ml in 1ml	0.5	211	0	105.5	0.1055	365	0.000289041	0.106
Precursors	Ergometrine Injection 0.5mg/ml in 1ml	0.5	253	0	126.5	0.1265	365	0.000346575	0.127
Precursors	Ergometrine Injection 0.5mg/ml in 1ml	0.5	230	0	115	0.115	365	0.000315068	0.115
Precursors	Ergometrine Injection 0.5mg/ml in 1ml	0.5	210	0	105	0.105	365	0.000287671	0.105
Precursors	Ergometrine Tablet 0.5mg	0.5	80	0	40	0.04	365	0.000109589	0.040
Precursors	Ergometrine Tablet 0.5mg	0.5	70	0	35	0.035	365	9.58904E-05	0.035
Precursors	Ergometrine Tablet 0.5mg	0.5	40	0	20	0.02	365	5.47945E-05	0.020
Precursors	Ephedrine Injection 30mg/ml in 1ml	30	120	0	3600	3.6	365	0.009863014	3.600
Precursors	Ergometrine Injection 0.2mg/ml in 1ml	0.2	1101	0	220.2	0.2202	365	0.000603288	0.220
Precursors	Pseudoephedrine Syrup 30mg/5ml in 50ml	300	286	0	85800	85.8	365	0.235068493	85.800
Precursors	Pseudoephedrine Tablet 60mg	60	2496	0	149760	149.76	365	0.41030137	149.760

Psychotropic Substances	Bromazepam Tablet 3mg	3	240	63	720	0.72	302	0.002384106	0.870
Psychotropic Substances	Bromazepam Tablet 3mg	3	370	0	1110	1.11	365	0.003041096	1.110
Psychotropic Substances	Diazepam Injection 10mg/2ml in 2ml	10	18	0	180	0.18	365	0.000493151	0.180
Psychotropic Substances	Diazepam Injection 5mg/ml in 2ml	10	11	0	110	0.11	365	0.00030137	0.110
Psychotropic Substances	Diazepam Injection 5mg/ml in 2ml	10	18	0	180	0.18	365	0.000493151	0.180
Psychotropic Substances	Diazepam Tablet 5mg	5	73	0	365	0.365	365	0.001	0.365
Psychotropic Substances	Diazepam Tablet 5mg	5	77	0	385	0.385	365	0.001054795	0.385
Psychotropic Substances	Diazepam Tablet 5mg	5	82	0	410	0.41	365	0.001123288	0.410
Psychotropic Substances	Phenobarbitone Tablet 30mg	30	68	0	2040	2.04	365	0.005589041	2.040
Psychotropic Substances	Phenobarbitone Tablet 30mg	30	82	0	2460	2.46	365	0.006739726	2.460
Psychotropic Substances	Phenobarbitone Tablet 30mg	30	88	0	2640	2.64	365	0.007232877	2.640
Psychotropic Substances	Bromazepam Tablet 3mg	3	30	0	90	0.09	365	0.000246575	0.090
Psychotropic Substances	Bromazepam Tablet 3mg	3	10	0	30	0.03	365	8.21918E-05	0.030
Psychotropic Substances	Diazepam Injection 10mg/2ml in 2ml	10	2	0	20	0.02	365	5.47945E-05	0.020
Psychotropic Substances	Diazepam Tablet 5mg	5	47	0	235	0.235	365	0.000643836	0.235
Psychotropic Substances	Amitriptyline Tablet 25mg	25	5530	0	138250	138.25	365	0.378767123	138.250
Psychotropic Substances	Bromazepam Tablet 1.5mg	1.5	2710	0	4065	4.065	365	0.011136986	4.065
Psychotropic Substances	Bromazepam Tablet 3mg	3	3077	0	9231	9.231	365	0.025290411	9.231

Psychotropic Substances	Diazepam Injection 10mg/2ml in 2ml	10	934	0	9340	9.34	365	0.025589041	9.340
Psychotropic Substances	Diazepam Tablet 5mg	5	2210	0	11050	11.05	365	0.030273973	11.050
Psychotropic Substances	Ketamine Injection 50mg/ml in 10ml	500	272	0	136000	136	365	0.37260274	136.000
Psychotropic Substances	Nitrazepam Tablet 5mg	5	390	0	1950	1.95	365	0.005342466	1.950
Psychotropic Substances	Pentazocine Injection 30mg/ml in 1ml	30	3856	0	115680	115.68	365	0.316931507	115.680
Psychotropic Substances	Phenobarbitone Injection 100mg/ml in 1ml	100	400	0	40000	40	365	0.109589041	40.000
Psychotropic Substances	Phenobarbitone Syrup 15mg/5ml in 60ml	180	47	0	8460	8.46	365	0.023178082	8.460
Psychotropic Substances	Phenobarbitone Tablet 30mg	30	1820	0	54600	54.6	365	0.149589041	54.600
Psychotropic Substances	Bromazepam Tablet 1.5mg	1.5	50	0	75	0.075	365	0.000205479	0.075
Psychotropic Substances	Bromazepam Tablet 3mg	3	100	0	300	0.3	365	0.000821918	0.300
Psychotropic Substances	Diazepam Injection 5mg/ml in 2ml	10	500	0	5000	5	365	0.01369863	5.000
Psychotropic Substances	Diazepam Injection 5mg/ml in 2ml	10	100	0	1000	1	365	0.002739726	1.000
Psychotropic Substances	Diazepam Tablet 5mg	5	1000	0	5000	5	365	0.01369863	5.000

Annex 6: Example showing calculation of psychotropic substances and precursors over a 3 year period with 10% mark-up

Drugs	Minimum estimate: projection from state quantities (A)					Maximum estimate: projection using total numbers of health facilities across country (B)				
	Estimated Consumption (kg)			Estimated annual national consumption for each Drug strength in Kg	Annual consumption with 10% Mark up in Kg	Estimated Consumption (kg)			Estimated annual national consumption for each Drug strength in Kg	Annual consumption with 10% Mark up in Kg
	2014	2015	2016			2014	2015	2016		
Precursors										
Ephedrine Injection 30mg/ml in 1ml	2.8399	9.1501	2.7455	9.8417	10.8258	21.5970	221.1292	17.5724	219.3272	241.2599
Ephedrine Syrup 3mg/5ml in 100ml	1.4672	0.4451	1.0079	1.1288	1.2417	36.6902	11.1307	13.6024	18.7565	20.6321
Ephedrine Syrup 6mg/5ml in 100ml	22.0974	25.0976	24.4464	23.8558	26.2413	39.4127	38.5283	47.4788	41.9776	46.1754
Ergometrine Injection 0.5mg/ml in 1ml	3.6587	0.9909	2.1521	3.1419	3.4560	7.2384	2.5889	4.7698	4.7760	5.2536
Ergometrine Injection 0.5mg/ml in 2ml	0.0290	0.0270	0.0479	0.0336	0.0370	1.7517	1.6854	2.8668	1.9545	2.1499
Ergometrine Tablet 0.5mg	0.0062	0.4986	0.0058	0.4989	0.5488	0.3916	14.8810	0.5584	14.9599	16.4559
Ergometrine Tablet 1mg	0.5676	0.4186	0.6835	0.5015	0.5517	16.9407	12.3319	20.1361	14.9937	16.4930
Ergotamine Injection 0.5mg/ml in 1ml	0.5713	0.6582	0.5827	0.6332	0.6965	8.5799	11.3700	11.9192	12.8040	14.0844
Ergotamine Injection 0.5mg/ml in 2ml	0.0000	0.0000	0.0157	0.0157	0.0172	0.0000	0.0000	1.2787	1.2787	1.4066
Ergotamine Tablet 0.5mg	0.5523	0.0045	0.0229	0.5541	0.6095	8.2911	0.2323	1.1292	5.8676	6.4543
Ergotamine Tablet 1mg	0.1413	0.1413	0.1932	0.2011	0.2212	1.8344	1.6052	2.2443	2.3018	2.5319
Ergotamine Tablet 2mg	0.0000	0.0038	0.0152	0.0095	0.0105	0.0000	0.3034	1.2137	0.7586	0.8344
Pseudoephedrine Syrup 15mg/5ml in 100ml	0.8725	22.3921	2.9289	6.7665	7.4431	427.0042	10959.3506	1433.4885	3311.7119	3642.8831

Pseudoephedrine Syrup 15mg/5ml in 50ml	0.0000	0.0000	1.9800	1.9800	2.1780	0.0000	0.0000	102.7800	102.7800	113.0580
Pseudoephedrine Tablet 60mg	87.4139	103.8415	75.1513	99.6581	109.6239	599.8219	798.9076	781.5846	691.7633	760.9396
Psychotropic Substances										
Amitriptyline Tablet 25mg	477.5723	472.6106	488.7665	495.7710	545.3481	1383.4759	1440.4028	1486.5044	1503.7329	1654.1062
Amitriptyline Tablet 50mg	2.7775	2.8100	4.2860	3.7975	4.1772	38.9234	62.5560	47.6919	48.6168	53.4785
Bromazepam Tablet 1.5mg	14.2027	12.4318	6.4620	12.4473	13.6920	77.9620	32.2898	15.4722	33.8815	37.2697
Bromazepam Tablet 3mg	60.8686	17.7374	25.7118	35.2378	38.7616	271.8406	41.0831	62.1602	106.1599	116.7759
Clomipramine Tablet 25mg	1.8352	0.1008	0.7416	1.3929	1.5322	43.6624	4.3462	17.7799	22.2781	24.5059
Clomipramine Tablet 75mg	0.0000	0.0210	0.0000	0.0210	0.0231	0.0000	0.8820	0.0000	0.8820	0.9702
Clonazepam Tablet 2mg	0.0303	0.0525	0.0358	0.0517	0.0569	0.9799	1.7082	1.2940	1.5119	1.6631
Diazepam Injection 10mg/2ml in 2ml	18.8711	15.6352	15.7237	19.7057	21.6763	115.5285	116.4294	50.2988	88.1337	96.9471
Diazepam Tablet 5mg	228.7818	157.7250	152.7595	184.4081	202.8490	338.7442	236.6867	166.8930	244.2489	268.6738
Flunitrazepam Tablet 1mg	0.0725	0.0730	1.4749	1.4733	1.6206	1.3459	1.1254	1.8688	1.5106	1.6617
Ketamine Injection 10mg/ml in 20ml	0.1100	0.0740	0.0540	0.0793	0.0873	4.6200	3.1080	2.2680	3.3320	3.6652
Ketamine Injection 50mg/ml in 10ml	180.0438	630.6890	503.6128	508.6750	559.5425	1402.0656	3601.6767	2957.0450	2784.7737	3063.2511
Ketamine Injection 50mg/ml in 1ml	0.0000	0.1000	0.0000	0.1000	0.1100	0.0000	4.2000	0.0000	4.2000	4.6200
Lorazepam Tablet 1mg	0.0269	0.1039	0.0000	0.0778	0.0856	0.0548	0.4996	0.0000	0.3443	0.3787
Lorazepam Tablet 2mg	0.0483	0.0401	0.0453	0.0494	0.0544	0.5560	0.3009	0.2817	0.3752	0.4127
Lorazepam Tablet 3mg	0.4309	0.4504	0.3858	0.4224	0.4646	5.0350	5.2627	4.5075	4.9351	5.4286
Methylphenidate Tablet 10mg	0.7986	0.3936	1.4308	0.8743	0.9618	9.5829	4.7233	17.1696	10.4919	11.5411
Midazolam Injection 5mg/ml in 1ml	0.1092	0.0605	0.0530	0.0732	0.0805	1.3266	0.4775	0.5951	0.7210	0.7931
Midazolam Injection 5mg/ml in 3ml	0.3212	0.3339	0.6484	0.4807	0.5287	2.1201	4.9619	4.9884	4.1819	4.6001
Nitrazepam Tablet 10mg	0.5456	0.0000	0.0000	0.5456	0.6002	4.4959	0.0000	0.0000	4.4959	4.9455
Nitrazepam Tablet 5mg	115.6330	113.4742	101.2101	110.8764	121.9641	558.4965	560.7656	351.6835	480.1150	528.1265
Pentazocine Injection 15mg/ml in 2ml	0.1428	0.4050	0.6276	0.4289	0.4718	5.6493	14.6658	21.1872	16.2527	17.8780

Pentazocine Injection 30mg/ml in 1ml	1748.8851	197.2080	366.2641	782.1132	860.3245	3216.3135	497.0315	1292.9131	1690.8730	1859.9603
Phenobarbitone Injection 15mg/ml in 2ml	0.0293	0.0500	0.0702	0.0498	0.0548	0.9840	1.6798	2.3581	1.6739	1.8413
Phenobarbitone Injection 200mg/ml in 1ml	179.3083	38.0736	85.6272	181.6241	199.7865	3198.3759	667.2759	2347.7971	2196.8149	2416.4964
Phenobarbitone Syrup 15mg/5ml in 100ml	2.3219	6.6612	5.0189	6.0888	6.6976	74.8921	66.2735	81.1130	72.0664	79.2730
Phenobarbitone Syrup 15mg/5ml in 60ml	83.3121	95.1718	109.8210	97.1121	106.8233	212.8274	700.4458	993.0623	722.3431	794.5774
Phenobarbitone Tablet 100mg	2.6309	4.3680	2.6208	3.2066	3.5272	99.0487	164.4480	98.6688	120.7218	132.7940
Phenobarbitone Tablet 15mg	10.2000	10.9536	10.2000	10.9536	12.0490	227.5650	126.8793	227.5650	177.2221	194.9444
Thiopentone Injection 500mg/10ml in 10ml	2.2775	2.1377	2.8176	3.2599	3.5859	6.3211	10.8604	15.6220	10.7250	11.7975
Thioridazine Tablet 100mg	0.3600	0.3400	0.8598	0.6931	0.7624	7.5600	7.1400	42.9864	25.3464	27.8810
Thioridazine Tablet 50mg	0.8602	0.2995	0.0000	0.7299	0.8029	10.3618	5.5936	0.0000	8.4546	9.3000

Annex 7: Instrument for estimation of psychotropic substances and precursors for manufacturers, importers and exporters

Method: Consumption-based method (*This should be completed at the end of the year being reported on*)

Name of company: …… Ownership: (public, private, etc): …….

Status (manufacturer / Importer / exporter): …… Address: ……..

Year under review: ……

S. No.	Drug Substance	Qty Imported (kg)	Qty Used for Manufact. (kg)	Total Qty of Finished Product (kg)	Qty Distributed (kg) -- Finished pdt [Internally]	Qty Exported (kg) -- Finished pdt [External]	Qty in stock – Raw Mat. (kg) [closing bal]	Qty in Stock – Finishd pdt (kg) [closing bal]	Products Manufactured (Brand Names) [form/strength]	Remarks (Expired finished pdt, Expired Raw Mat, QC Rejects, Recall or returns, Customer rejects, etc. in Kg)
Labels	**E.g. Codeine**	**A**	**B**	**C**	**D**	**E**	**F**	**G**		
1										
2										

Additional information or observations made whiles gathering data:

Drug substance (means pharmaceutical products containing psychotropic substances/precursors):

- ✓ **Psychotropic substances**: *Benzodiazepines* (Diazepam, Flunitrazepam, Bromazepam, Chlordiazepoxide, Nitrazepam, Lorazepam, Alprazolam, Midazolam, Clonazepam); *Barbiturates* (Phenobarbitone, Pentobarbitone, Thiopentone); *Methylphenidate*; *Ketamine*
- ✓ **Precursors**: Pharmaceutical products containing *Ephedrine* and *Pseudoephedrine*; *Ergotamine*; *Ergometrine*

Form completed by (Name and position):

Submission approved by (Name and position):

Date form submitted:

NB: Data should be collected over **three** consecutive years

Annex 8: The administration of the system of estimates and assessments for psychotropic substances and precursors

Key steps in the administration of estimates and assessments [1]

	Estimates for narcotic drugs	Assessment for psychotropic substances	Estimates for precursors
Form used	B	B/P	D
Frequency of submission	Once a year	At least once every three years	Once a year
Submission deadline	30 June of the previous year	Any time	30 June of the previous year
Confirmation by INCB required	Yes	No	No
Validity	One year	Until amended, but preferably three years	Until amended, but preferably one year
Related publication and information source	INCB technical publication and website	INCB technical publication and website	INCB precursors report and website
Amendments possible	Yes, throughout the year	Yes, any time	Yes, throughout the year
Forms for amendments	Supplement to form B	B/P	Official correspondence from Government
Publication of amendments	Monthly on INCB website and quarterly in print	Monthly on INCB website and quarterly in print	As required, on INCB website

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1: INCB & WHO (2012). Guide on Estimating Requirements for Substances under International Control

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