



Compilation of Methodologies for Collecting Data on the Consumption of Psychotropic Substances



Acknowledgements

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I. Introduction

Background information

1. In the preamble to the Convention on Psychotropic Substances of 1971,¹ it is recognized that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted. The International Narcotics Control Board (INCB) is committed to supporting Governments in the attainment of well-balanced access to those substances with due consideration of all requirements for medical and scientific purposes.
2. The 1971 Convention does not provide a definition of consumption of psychotropic substances falling under its control regime. To that end, the Commission on Narcotic Drugs adopted multiple resolutions aimed at increasing the Board's cooperation with Governments in gaining a clearer picture of the levels of consumption of psychotropic substances worldwide.
3. At its fifty-third session, held in March 2010, recalling the preamble to the 1971 Convention, the Commission on Narcotic Drugs, in its resolution 53/4, invited the Board to include in its annual report for 2010 information on the consumption of psychotropic substances.
4. A year later, in 2011, the Commission on Narcotic Drugs, in its resolution 54/6, encouraged Member States to report data on the consumption of psychotropic substances for medical and scientific purposes to INCB in the same manner as they report on narcotic drugs.
5. The outcome document of the thirtieth special session of the General Assembly, held in 2016, entitled "Our joint commitment to effectively addressing and countering the world drug problem",² contains what is probably the most imperative statement by the United Nations to date in relation to the collection of data on the consumption of controlled substances used for medical and scientific purposes.
6. Finally, in 2019, the Commission on Narcotic Drugs, in its resolution 62/5, welcomed the initiative of Member States, INCB and the United Nations Office on Drugs and Crime (UNODC) to facilitate, including by convening expert consultations of the staff of competent national authorities, the sharing of experiences and good practices on the submission of data on the consumption of psychotropic substances on a voluntary basis.
7. In the light of the difficulties encountered by the competent national authorities of many countries in collecting and calculating consumption data for psychotropic substances, the Board, in its decision 126/11, adopted in November 2019, assigned the secretariat the task of reaching out to countries that submit consumption data, requesting them to provide information on the methodology used in the collection process and convening an expert group meeting to explore the possibility of developing guidelines on reporting the consumption of psychotropic substances.
8. Following the Board's request, the secretariat decided to convene an online expert group meeting from 14 to 17 September 2020. In addition to the participation and contributions of competent

¹ United Nations, *Treaty Series*, vol. 1019, No. 14956.

² General Assembly resolution S-30/1, annex.

national authorities from 20 countries,³ representatives of four international organizations took part as guest speakers, namely, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the Pan American Health Organization, UNODC and the World Health Organization (WHO).

Scope and objectives of the compilation

9. The present document contains a summary of the information submitted by competent national authorities in response to a circular letter dated 4 February 2020 and is complemented by material obtained from recordings of the discussions held during the expert group meeting from 14 to 17 September 2020, including presentations given by the guest speakers and information extracted from official documents issued by the United Nations and INCB.

10. The information provided in the present document is intended to serve as the starting point for the development of data collection methodologies by competent national authorities that do not report data on the consumption of psychotropic substances to INCB. It also covers the benefits of having a reliable data collection process and using consumption data for purposes other than reporting.

11. The document also includes a discussion of the mechanisms used by some competent national authorities to validate the data collected from their licensed operators. Finally, it provides information about common operational practices in the data collection process that were deemed relevant during the expert group meeting, and about how new technologies are shaping the future of health information systems and how Governments can benefit from them.

12. Throughout the document, it is assumed that the distribution of psychotropic substances in each part of the distribution circuit is carried out in a licit and regulated market, and consumption refers to the taking of psychotropic substances, or medicines containing psychotropic substances, for medical and scientific purposes.

Psychotropic substances and public health

13. The United Nations recognizes that there can be no sustainable development without good health and well-being for all humankind. Leaving no one behind requires a strong commitment from the entire United Nations system and all Member States to promote better health systems, improved access to medicines and physicians, and higher sanitation and hygiene standards. At least five targets under Sustainable Development Goal 3, on good health and well-being, are linked directly to the promotion of mental health and the appropriate treatment of related disorders (i.e., targets 3.4, 3.5, 3.8, 3.b and 3.d).

14. Mental and behavioural disorders, such as anxiety, depression, schizophrenia and bipolar disorder, affect all groups in society. The same is true of conditions such as epilepsy or conditions in which convulsions are among the symptoms.

15. In that regard, WHO defines essential medicines as “those that satisfy the priority health care needs of the population”.⁴ It also states that those medicines should always be available in adequate amounts, in the appropriate dosage, with assured quality and at an affordable price. Currently, five

³ Argentina, Belgium, Chile, Costa Rica, Finland, Germany, Jamaica, Latvia, Lithuania, Mexico, Montenegro, Netherlands, New Zealand, Peru, Singapore, Spain, Sweden, Switzerland, United States of America, and Zimbabwe.

⁴ See www.who.int/medicines/services/essmedicines_def/en/.

psychotropic substances are included in the WHO Model List of Essential Medicines, namely, buprenorphine, diazepam, lorazepam, midazolam and phenobarbital.

16. The importance of making internationally controlled drugs available for medical and scientific purposes is enshrined in the preamble to the 1971 Convention and has been reaffirmed in policy documents in recent years, including in the outcome document of the special session of the General Assembly on the world drug problem held in 2016.

17. There are significant concerns regarding the consumption and accessibility of psychotropic substances, which are necessary in the treatment of a range of serious health conditions. According to the 2015 INCB special report entitled *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes – Indispensable, Adequately Available and Not Unduly Restricted*,⁵ mental disorders afflict hundreds of millions of people and their families, but the resources available in most countries to treat such conditions are insufficient. The vast majority of countries allocate less than 2 per cent of their health budgets to mental health, leaving more than 75 per cent of the population in many low- and middle-income countries with no access to such treatment.

18. Levels of consumption of psychotropic substances, which are used for the treatment of mental and neurological disorders, such as anxiety, insomnia and epilepsy, continue to vary widely among countries and regions. As mentioned in the 2018 INCB special report entitled *Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes*, while 80 per cent of people living with epilepsy live in low- and middle-income countries, the consumption of related psychotropic substances is concentrated in high-income countries.⁶ This reflects on the one hand a diversity in medical practice and related variations in prescription patterns, and on the other hand a lack of accurate data, both quantitative and qualitative, on the consumption of such substances.

19. The parties to the 1971 Convention, while expressing a determination to prevent and combat abuse of and trafficking in psychotropic substances, recognized that the use of such substances for medical and scientific purposes was indispensable and that their availability for such purposes should not be unduly restricted.

20. The consumption data related to psychotropic substances, as submitted to the Board, show disparities among countries and regions in the levels of consumption of such substances. Inadequate availability of and poor access to necessary medical treatment, as well as excessive availability and medically unsound use of psychotropic substances, all pose challenges to their control and use.

21. The Board is mandated by the international drug control conventions to monitor the availability of internationally controlled substances for medical and scientific purposes, while preventing trafficking in and abuse of those substances. In that regard, the Board has noted that inadequate availability and poor access to necessary medical treatments, as well as excessive availability and unsound medical use of psychotropic substances, represent threats to the control and rational use of such substances, in particular for the treatment of mental health and neurological conditions.

22. In addition, the lack of data on the quantities of psychotropic substances controlled under the 1971 Convention that are consumed in many parts of the world remains the main challenge in assessing

⁵ E/INCB/2015/1/Supp.1.

⁶ E/INCB/2018/1/Supp.1, chap. III.

and analysing trends in their availability and providing appropriate assistance to countries where availability is low.

II. Consumption of psychotropic substances and assessment of their availability for medical purposes

23. Assessing the availability of psychotropic substances for medical and scientific purposes depends largely on the availability of adequate, reliable and accurate consumption data. Unlike for narcotic drugs, the submission of national consumption data for psychotropic substances is not an obligation under the 1971 Convention, and countries that do provide this set of data do so on a voluntary basis pursuant to Commission on Narcotic Drugs resolution 54/6.

24. Over the past eight years, the Board has received consumption data, albeit of varying quality, from an increasing number of countries. In 2019, some 80 countries provided to the Board their national consumption data for at least one psychotropic substance. While the amount of data submitted varies significantly across the regions of the world, the considerable increase in the voluntary submission of data on the consumption of psychotropic substances has allowed the Board to take initial steps in analysing the availability of those important substances for medical purposes. The Board published the related findings in its 2018 special report entitled *Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes*. The same report concludes that quality data on the consumption of psychotropic substances are the key to a comprehensive assessment of the global availability of psychotropic substances.

25. In 2018, UNODC published an advance draft of a guide entitled *Technical Guidance: Increasing Access to and Availability of Controlled Medicines*. The guide provides information on several practical strategies that Governments might adopt to address the adverse effects resulting from unduly restricted or inadequate access to controlled substances. It also elaborates on five cross-cutting themes that are defined as crucial in developing actionable strategies. The cross-cutting theme relating to data and research highlights the relevance of quality data and research in driving evidence-based policies and interventions. In connection with that theme, the document includes a list of 14 action points, which included prioritizing the collection of accurate data at all levels of the health-care system; improving and institutionalizing data collection on the consumption of controlled medicines at the local and national levels; and expanding data collection beyond retail consumption to include dispensing and end user consumption.

26. To continue this work, data collection based on reliable methodology that is suited to each country's needs is of utmost importance. As the 1971 Convention does not provide a definition of consumption of psychotropic substances falling under its control regime, figure I elaborates on the definition of consumption and what is regarded as consumed under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. Some parallels can be drawn when defining the distribution circuits for each type of substance; however, they should not be considered to be identical. For example, the national legal framework in a country or territory may regulate the management and distribution of psychotropic substances and narcotic drugs differently, allowing competent national authorities to collect different data at different points. Figure II depicts the distribution circuit of psychotropic substances and the possible data collection points and reporting sources.

27. The various methodologies for collecting consumption data that have been identified and compiled in the present document are discussed in chapter III.

Figure I. Consumption as defined in the Single Convention on Narcotic Drugs of 1961

Consumption of narcotic drugs

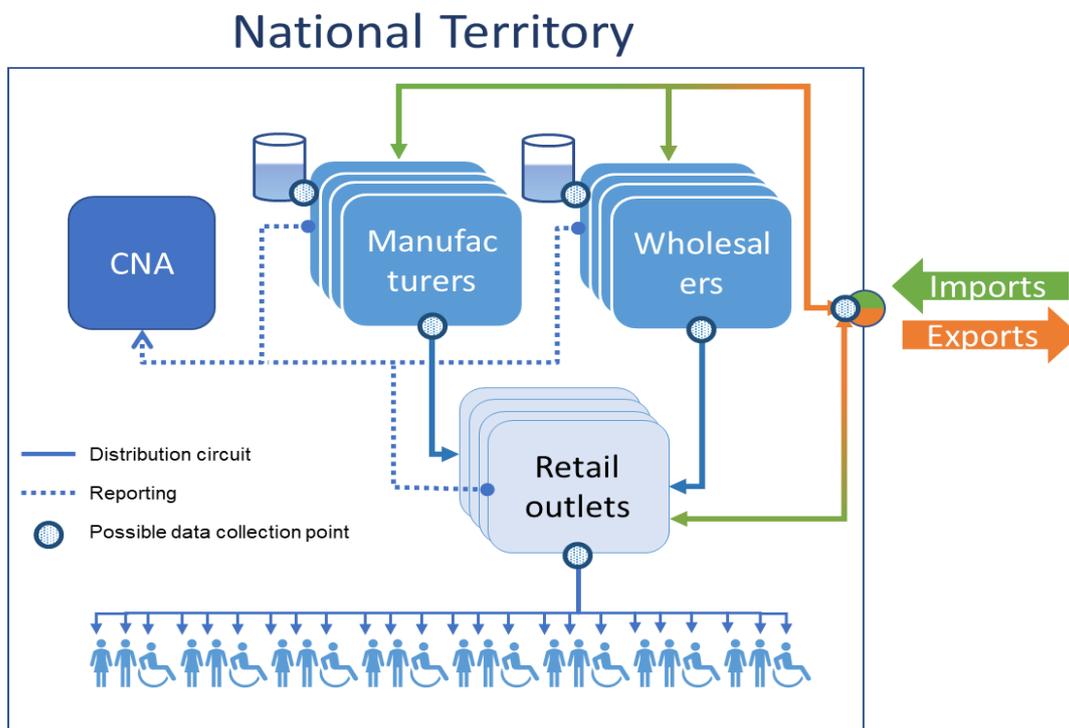
The Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, introduced the concept of drug “consumption” for narcotic drugs. In article 1, paragraph 2, of the Convention, it is stated that “a drug shall be regarded as ‘consumed’ when it has been supplied to any person or enterprise for retail distribution, medical use or scientific research; and ‘consumption’ shall be construed accordingly”.

The International Narcotics Control Board provided further information in its training material on the 1961 Convention (Part 2: The estimates system for narcotic drugs):

Consumption is therefore defined as the transfer from wholesale to retail distribution. Consequently, if narcotic drugs are imported into a country or territory directly by retailers (pharmacists, hospitals, etc.), all quantities so imported should be considered, from the Convention’s point of view, as consumed during the year of their entry into the country or territory. If, on the other hand, there is a manufacturer or wholesaler (whether a private enterprise or a government service) through which all narcotic drugs are imported, only that part of narcotic drugs distributed to the retail level (mainly pharmacies and hospitals) should be considered as consumed.

As such, the concept of the “consumption” of narcotic drugs can be illustrated in three different distribution circuits:

- *Category I: countries where retailers obtain their supplies solely from abroad. In this case, all quantities imported are regarded as consumed.*
- *Category II: countries where retailers obtain their supplies solely from local manufacturers or wholesalers. In this case, quantities consumed refer to those quantities distributed by the manufacturers or wholesalers to the retailers.*
- *Category III: countries where the retailers obtain their supplies mainly from local manufacturers or wholesalers, but where some retailers import psychotropic substances or narcotic drugs directly. In this case, quantities consumed refer to those quantities distributed by manufacturers or wholesalers to the retailers, plus the quantities imported directly by retailers.*

Figure II. Distribution circuit of psychotropic substances

III. Data collection methodologies

A. General observations

28. Methodologies implemented for the collection of data on the consumption of psychotropic substances differ from country to country. Various elements, such as policies, infrastructure and technology, may influence the number and nature of the instruments used to collect data, not only in the realm of internationally controlled substances but also in general. Some competent national authorities may find it easy to tip certain elements in one direction or another, while others may face constraints that cannot be changed.

29. Competent national authorities are immersed in nationwide structures and are subject to a set of rules that are broader in scope than their own organizations, including national regulatory frameworks, legacy practices and systems, the corporate climate and government infrastructure, to name but a few examples.

30. If the methodology implemented by a competent national authority is backed by explicit policies that allow it to collect data from private and public organizations licensed to handle psychotropic substances, it is certainly easier than implementing a data collection methodology backed by a less stringent regulatory framework. Moreover, national policies that include mechanisms for streamlining data collection instruments can help competent national authorities to improve the quantity and quality of data collected.

31. Offices in charge of collecting data on internationally controlled substances may have at their disposal elaborate systems or tools to gather, process, store, organize and even analyse data.

Sometimes, however, that is not the case, and the system may be as straightforward as a physical or electronic repository of files with some sort of classification scheme. Each of those approaches serves its own purpose.

32. The relationship maintained by the competent national authority with the organizations that provide data on the consumption of psychotropic substances is another element that may affect the data collection process. Regular follow-up and capacity-building activities appear to be a particularly successful practice in maintaining and improving the quality and timeliness of data.

33. In the previous chapter, three distribution circuits of internationally controlled substances were listed. Those circuits are tied to the supply source that feeds directly into retail outlets and, on the basis of the definition of “consumption”, are closely related to the data collection mechanisms presented below. Although they were initially developed in connection with the consumption of narcotic drugs, the underlying concepts can be expanded to the collection of data on psychotropic substances.

B. Considerations for competent national authorities

National legal framework for data collection

34. Competent national authorities may enjoy varying degrees of operational freedom in engaging with their reporting operators based on the national legal frameworks in which they operate. It is important to consider those statutory foundations, as they may provide tools to manoeuvre and to address certain operational and administrative challenges, but they may also impose restrictions that are difficult to circumvent. From an organizational perspective, the mandate of the reporting competent national authority could be closely tied to the office in charge of promoting the national health system, or it could be aligned with law enforcement principles. Regardless of the legal framework governing the operations of the competent national authority, it should not lose focus on the reasons underlying the data collection process.

Resources, information technology infrastructure and reporting cycles

35. Reporting authorities should, unquestionably, plan the resources allocated to collect, process and analyse data. The more diverse the data sources are, the more complex the process is, and the more resources should be devoted to such efforts. Investments in information technology infrastructure have proved to be helpful in improving the reporting capacity of competent national authorities. As such investments are not always affordable, some offices rely on basic information technology systems or even manual data collection and verification processes. Regardless of the available resources, there seems to be a consensus that, instead of collecting and processing consumption data once per year, it is more efficient to carry out the process in shorter cycles, for example on a biannual, quarterly or even monthly basis. The underlying reason appears to be that shorter reporting periods generate more manageable amounts of data, reducing the risk of inconsistencies and improving the oversight of non-compliant reporting operators.

36. Increasing the frequency of reporting is not always enough if near real-time data on the consumption of psychotropic substances are needed. The coronavirus disease (COVID-19) pandemic is a clear example. Policymakers, and hence competent national authorities in charge of collecting consumption data, could not wait three months – or even one month – to take corrective actions in order to address possible medicine shortages. In this situation, evidence-based decisions are required to optimize the resources needed to stockpile the correct set of substances. The quantification of substances and medicines imported to a country or territory has been identified as one of the

mechanisms to fill this information gap. Even though in many cases imports cannot be equated to consumption, there is a direct and proportional link between the two elements. As import authorizations should be channelled through a country's competent national authority, it should take relatively little time and effort to collect and process the quantities of psychotropic substances imported into a country or territory and to provide a well-founded estimate of consumption levels.

37. The trendspotter methodology is another good example of a rapid assessment tool. Developed by EMCDDA, it is described as a tool to “map and describe a new drug trend or an emerging phenomenon, understand the drivers behind this change and identify implications for the future”.⁷ The methodology involves four main steps: (a) planning; (b) data collection and analysis (phase 1); (c) data collection and analysis (phase 2): the expert meeting; and (d) reporting, and it has recently been used by EMCDDA to assess the effects of the COVID-19 pandemic on drug consumption patterns in Europe.⁸

Definition of consumption

38. Streamlining the data collection methodology is another way to speed up the process. Several competent national authorities define the consumption of psychotropic substances in the same way as they do for narcotic drugs. This approach allows them to use the same methodology to collect data for both groups of substances with minor modifications, as it requires them only to expand the substance base furnished by reporting operators.

Capacity-building

39. It has also been noted that competent national authorities that conduct regular capacity-building activities with their reporting operators benefit from better quality and improved timeliness in the data furnished by those operators. Regular training also improves the operators' understanding of the legal framework in relation to internationally controlled substances, the relevance of the reported data and the legal obligations of competent national authorities.

Measures to ensure compliance

40. Some competent national authorities have highlighted the relevance of administrative measures to ensure adequate compliance with reporting obligations by licensed operators. Examples of such measures include withholding import or export authorizations, revoking licences or imposing fines. The means of enforcing such administrative measures are embedded in the legal framework in which the competent national authority operates. Some measures may be more or less stringent and/or easier to implement than others.

⁷ European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), *Trendspotter Manual: A Handbook for the Rapid Assessment of Emerging Drug-related Trends* (Luxembourg, Publications Office of the European Union, 2018).

⁸ EMCDDA, “EMCDDA trendspotter briefing: impact of COVID-19 on patterns of drug use and drug-related harms in Europe” (Luxembourg, Publications Office of the European Union, 2020).

C. Methodologies

1. Imports-only methodology

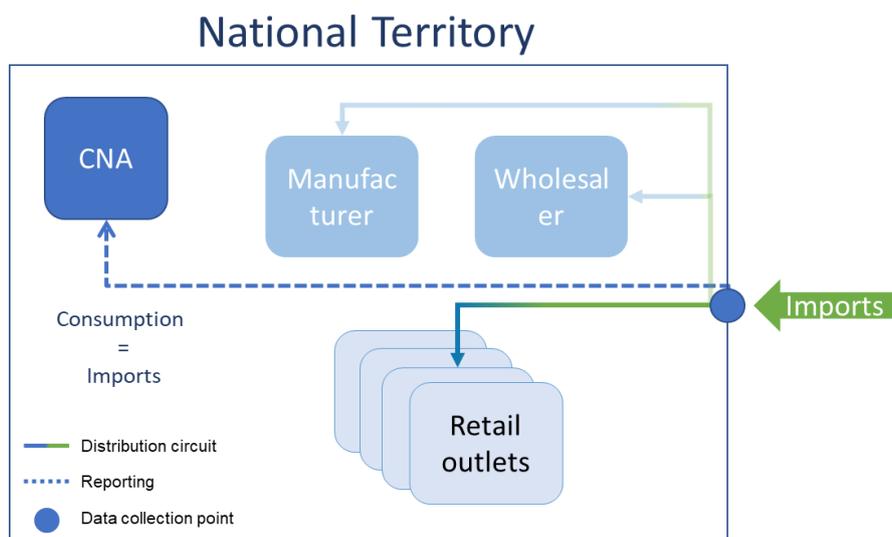
Characteristics of national market/distribution circuit

41. In this approach, the quantity of psychotropic substances imported is equated to the quantity considered (and reported) as consumed.

42. If a country or territory does not engage in wholesale trade or the manufacture of psychotropic substances, and retail outlets (e.g., pharmacies, retail distributors, hospitals and other institutions or qualified persons duly authorized to exercise therapeutic or scientific functions) obtain internationally controlled substances exclusively through imports, the quantities of psychotropic substances “consumed” will equal the quantities imported. However, this variant is also used in some countries where the substances are imported at the wholesale level and no data are collected downstream in the distribution circuit.

43. This methodology uses a single data collection point, namely, imports (see figure III). Quantities of psychotropic substances imported into a country or territory should be easily accessible to the reporting competent national authority. Other sources of information are considered in chapter IV, on validating consumption data, as the process of importing a psychotropic substance involves several actors, such as customs authorities, manufacturers, wholesalers and retail outlets.

Figure III. Consumption equal to imports



Advantages

44. This is the simplest data collection methodology. Its simplicity lies in the fact that competent national authorities are in control of the entire data collection process and there is just one data collection point. The key advantages of this methodology are as follows:

- (a) *Ease of data collection.* The data are readily available given that import authorizations for each psychotropic substance imported, including quantities, are issued and recorded by the competent national authority;

- (b) *Control of data quality and timeliness.* The competent national authority does not need to collect data from external organizations, a process that may introduce delays and/or reduce the quality and timeliness of the data;
- (c) *Disaggregated data on imports.* This approach can greatly improve the analysis of disaggregated data. If retail outlets are bound to specific geographical areas, population groups, etc., disaggregated data could become a valuable source of information.

Challenges

45. The following challenges have been identified:

- (a) The methodology can be applied only to very limited scenarios in which psychotropic substances are not imported by wholesalers or manufactured locally;
- (b) If wholesalers or manufacturers import psychotropic substances, it would be optimal to know the proportion of psychotropic substances (either from imports or from wholesalers or manufacturers) channelled to the retail market in order to obtain a more accurate overview of consumption in the country or territory;
- (c) The quantities authorized in an import authorization are not always equal to the amounts physically imported into a country or territory. Endorsement of each import authorization will improve the accuracy of the consumption data.

2. Calculated consumption based on indirect measurements

Characteristics of national market/distribution circuit

46. It is a common policy that licensed operators are required to furnish some type of activity reports to the competent national authority in the country in which they base their operations. The reporting schedule and length of such reports should be agreed upon by both parties and tied to the legal and operational requirements of the competent national authority. The more comprehensive the reports are, the more exhaustive the analysis of the information extracted from them will be.

47. Consumption can be calculated using aggregated data at the end of each reporting period. The formula most commonly used to calculate consumption is as follows:

$$\begin{aligned} \text{Consumption} &= [Q_{\text{stock,start}} + Q_{\text{manufactured}} + Q_{\text{imported}}] \\ &\quad - [Q_{\text{stock,end}} + Q_{\text{non-controlled substances}} \\ &\quad + Q_{\text{exported}}] \end{aligned}$$

Where:

$Q_{\text{stock, start}}$ = Quantities held in stock by manufacturers and wholesalers at the beginning of the year

$Q_{\text{manufactured}}$ = Quantities manufactured or produced domestically in the reporting year

Q_{imported} = Quantities imported during the reporting year

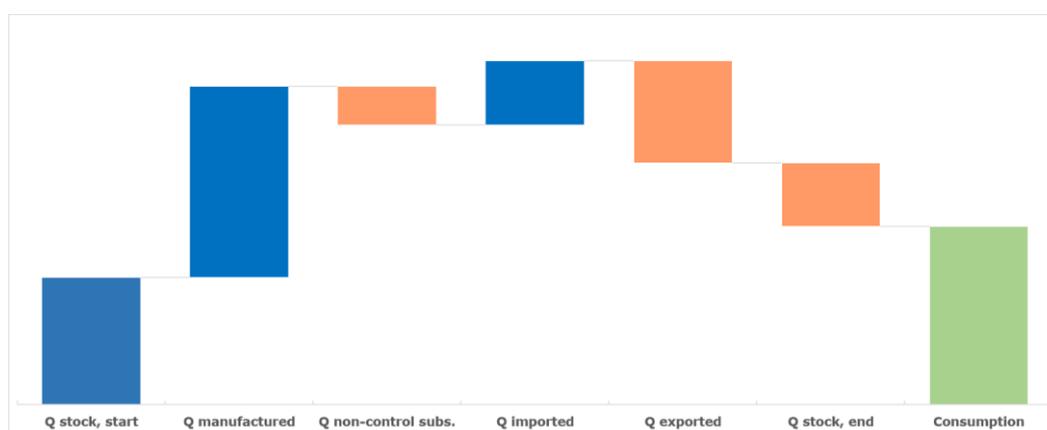
$Q_{\text{stock, end}}$ = Quantities held in stock by manufacturers and wholesalers at the end of the year

$Q_{\text{non-controlled substances}}$ = Quantities used for the manufacture of substances not under international control and/or disposed of in the reporting year

Q_{exported} = Quantities exported during the reporting year

48. The quantities added and subtracted in the formula are depicted in figure IV. The elements of the formula are redistributed in the figure not in order to represent the progression of consumption over the reporting period – commonly a calendar year – but to illustrate how the reporting authority could assume that the aggregated data between the starting and ending points represent the quantities consumed.

Figure IV. Calculated consumption breakdown



49. The starting amount in figure IV represents the quantities of psychotropic substances held in stock by manufacturers and wholesalers at the beginning of the year. It is assumed that those substances are ready to be consumed, but they may also be exported, disposed of or used in the manufacture of substances not under international control.

50. At any point in time, duly licensed organizations might manufacture psychotropic substances (raw materials, active pharmaceutical ingredients, preparations, etc.) within the national territory. Those quantities must be added to the equation, as it is assumed that they can be distributed to retail outlets at any time. Similarly, it is assumed that psychotropic substances imported during the reporting period are ready to be consumed, meaning that they must also be added to the equation.

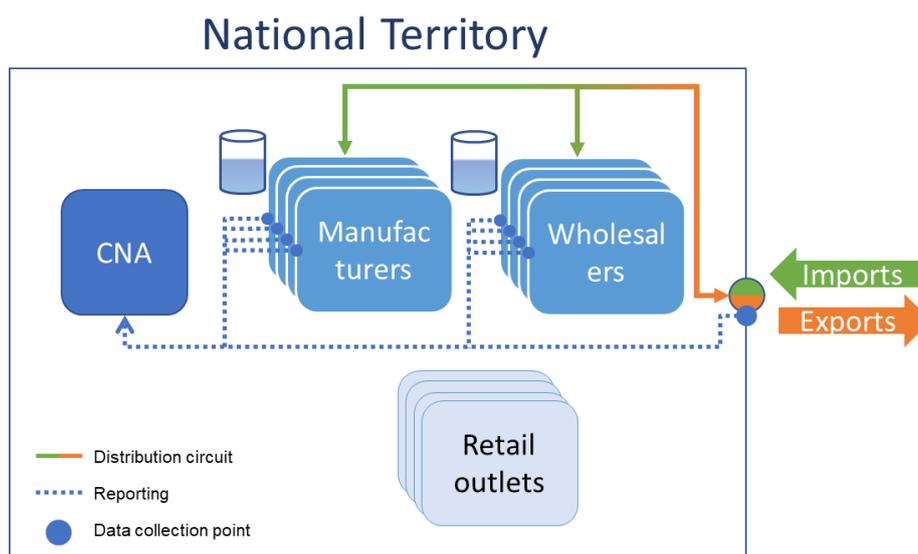
51. It is important to highlight that psychotropic substances manufactured by licensed operators could also be exported, disposed of or used in the manufacture of substances not under international control rather than being consumed. If that is the case, those quantities should be included in the amount shown in the second part of the formula above to reflect the corresponding event.

52. Psychotropic substances that are disposed of cannot be distributed to retail outlets, and those used in the manufacture of substances that are not under international control cannot be accounted for as consumed; hence, those quantities should also be subtracted. It is also necessary to subtract the quantities of psychotropic substances that are exported, as they are not consumed within the country or territory of the reporting authority. Finally, the quantities held in stock by manufacturers and wholesalers at the end of the year are to be deducted, as they were not consumed, exported or used in

the manufacture of substances not under international control or disposed of during the reporting period.

53. Quantities of psychotropic substances exported from or imported to the reporting country or territory can be calculated using data from the national authorization system administered by the competent national authority, on the basis of information provided by manufacturers and wholesalers, or using a combination of both (see figure V).

Figure V. Consumption based on indirect measurements



Advantages

54. In terms of complexity, this methodology is not as simple as equating consumption to all quantities imported during a reporting period; however, it can be applied to a much wider set of scenarios. It includes substances that are locally manufactured, disposed of and used in the production of substances not under international control, and an additional entry point in the distribution circuit is also considered, that is, substances imported by wholesalers and manufacturers. The advantages of this approach include the following:

- (a) *Relative simplicity.* Once the quantities of each of the variables in the formula are known, it is relatively simple to calculate estimated consumption during the reporting period;
- (b) *Disaggregated data on multiple variables.* If it is possible to obtain disaggregated data on some of the variables, it is likely that consumption trends or patterns can be analysed. For example, disaggregated data on imports may help to compare the proportion of substances (medicines) consumed directly by retail outlets with those distributed by wholesalers and manufacturers and to assess the impact on the price to the final consumer and, consequently, the accessibility of the substances;
- (c) *Coverage of different scenarios.* The methodology accounts for imports by different stakeholders, substances manufactured or disposed of locally, etc. This makes it a more

appropriate option for countries or territories that have more complex supply systems for psychotropic substances.

Challenges

55. As this methodology requires more information from different sources, certain challenges need to be considered:

- (a) Closer cooperation with local organizations is required, as data must be collected periodically following a clear schedule. Partial information may be irrelevant or highly inaccurate;
- (b) It is also necessary to provide continuous support and training for local organizations in order to guarantee standardized definitions. It is not possible to aggregate or compare values that are not based on the same definitions across all data sources. For example, quantities of imported psychotropic substances may be measured at the time of authorization, endorsement or physical entry into the country or territory of the reporting authority. The same applies to quantities exported;
- (c) It is an indirect measure. This methodology assumes that the gap between the stocks held by manufacturers and wholesalers at the beginning and at the end of the year, considering all possible increases (manufacture and imports) and decreases (clearances and exports), equals the quantities distributed to retail outlets, in other words “consumed”. This method determines the quantity of psychotropic substances theoretically available for consumption in the country or territory.

3. Distribution from wholesalers and manufacturers to retail outlets

Characteristics of national market/distribution circuit

56. Countries that engage in intensive local trade and in which the proportions of imports channelled to wholesalers/manufacturers and retail outlets is unknown, unpredictable and difficult to calculate may find it easier to assess consumption levels solely on the basis of quantities distributed from wholesalers and manufacturers to retail outlets.

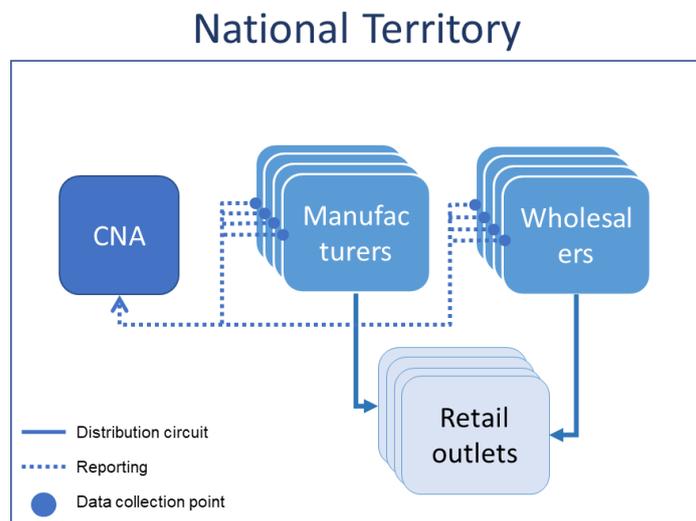
57. In this methodology, imports, exports, production, write-offs, stockpiles, etc., are not taken into account. Instead, wholesalers and manufacturers report to the reporting authority the quantities distributed downstream in the distribution circuit (see figure VI). Quantities distributed from wholesalers and manufacturers to retail outlets are a more accurate measure of consumption compared with those resulting from the indirect calculation methodology.

58. It is also necessary to note the technical challenges that a competent national authority may face in operating a statistical return system that collects data on the interface between wholesalers/manufacturers and retail outlets. For example, the distribution of psychotropic substances from the former to the latter usually does not trigger a data collection entry that is visible to the reporting authority. That information is typically collected and processed by the organizations involved in the transaction and then reported to the competent national authority.

59. It is therefore crucial to provide clarifications on the reporting exercise, the reporting cycle and the definition of consumption across all of the organizations licensed to distribute psychotropic

substances to retail outlets. Efforts in this regard will have a significant impact on the quality of the data received by the competent national authority and reported to INCB.

Figure VI. Distribution from wholesalers and manufacturers to retail outlets



Advantages

60. Competent national authorities do not need to operate complex and usually resource-intensive health information systems to implement this methodology. Nevertheless, the resulting figures provide an accurate representation of the quantities of psychotropic substances that are introduced into the local market and are consequently available to be consumed. The key advantages of this approach include the following:

- (a) *Balanced approach between complexity and accuracy.* It is important to highlight that there is no perfect data collection system and no single approach that serves all purposes. However, finding a balance between available resources and data quality is a key element to consider;
- (b) *Disaggregated data.* As is the case with the calculated consumption methodology, if consumption data are collected at some disaggregated level, it is possible to analyse certain trends and patterns. For example, a country might discover that the consumption of a specific medicine in one region (i.e., the quantities dispatched to certain retail outlets) is above or below the national average.

Challenges

61. The following challenges have been identified:

- (a) Psychotropic substances imported directly by retail outlets need to be considered separately. This does not pose a major challenge, as the reporting authority should be aware of and report all licit traffic in internationally controlled substances;

- (b) As is the case with the calculated consumption methodology, it is necessary to maintain close cooperation with the wholesalers and manufacturers that are licensed to distribute psychotropic substances in order to ensure a timely reporting system;
- (c) Continuous training and follow-up should be considered as a mechanism for standardizing definitions and processes across all stakeholders.

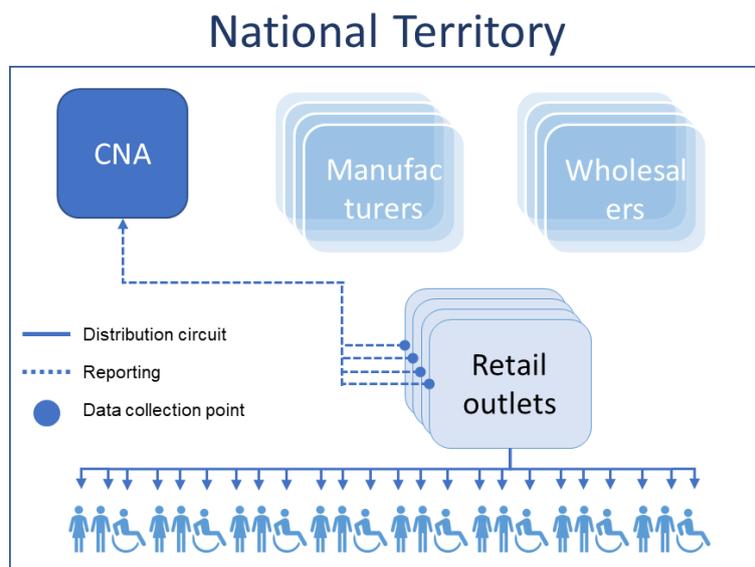
4. Distribution from retail outlets to the final user

Characteristics of national market/distribution circuit

62. Consumption data can be collected one step downstream in the distribution circuit, that is, on the basis of psychotropic substances handed over from retail outlets to the final user (see figure VII). Multiple data collection points should be considered if this methodology is to provide an accurate assessment of the consumption level. For example, psychotropic substances distributed to final users by health-care facilities, pharmacies, licensed practitioners (including veterinarians and dentists) and others should be included in the calculations. Collecting consumption data at the prescription level addresses the same situation from a different angle, that is, the data are collected at the receiving end of the transaction (the final user) rather than from the party supplying the psychotropic substance (the retail outlet). The way in which the health information system is designed to collect data will indicate which data collection points should be used in this methodology.

63. Given the extent and range of retail outlets operating in a country or territory, the collection of consumption data is very likely to be embedded in a wider health information system. Such systems usually operate at the national or regional level and collect information related to the final user, such as prescription data, doses, the physician or health centre responsible for the prescription, its validity period, etc.

64. Countries and territories that are in a position to implement such health information systems could collate, correlate and analyse consumption data with a great level of detail and accuracy. The more data are collected and analysed, the more information, trends and patterns can emerge. However, straightforward conclusions are not always obvious and, depending on the amount of data available, the process of analysis can be time-consuming. It is also important to highlight that, by taking advantage of modern technologies and computer processing power, competent national authorities could correlate such detailed data with data from other sources, such as demographics, to drive evidence-based conclusions and decisions.

Figure VII. Quantities distributed from retail outlets to the final user

Advantages

65. The closer the data collection point is to the final user, the more realistic the overview of the quantities of psychotropic substances consumed, in the literal sense of the word, by the population of a country or territory will be. Additional advantages of this method include the following:

- (a) *Data disaggregated by default.* As the data collected are already disaggregated, a great level of detail can be obtained and analysed;
- (b) *Increased accuracy.* The resulting figures provide a more precise overview of the quantities actually consumed by the population;
- (c) *Ease of correlating consumption with other data.* Consumption data are most likely to be collected as part of a national or regional health information system, which leads to the assumption that it can be correlated with other relevant data.

Challenges

66. The following challenges have been identified:

- (a) This methodology is relatively easy to implement if a health information system that collects data at the retail outlet level is already in place. In such a case, it should be necessary only to expand the data collected by the health information system to include data on the consumption of psychotropic substances. If the health information system were to collect data on the consumption of psychotropic substances only, the infrastructure required to gather such detailed information would make it difficult to implement;
- (b) The resources required to gather, process, store and analyse the data collected could be significantly higher than those required for other methodologies;

- (c) Quantities of psychotropic substances included in exempted preparations (e.g., medicines sold over the counter) may be difficult to record. If the health information system excludes exempted preparations from the distribution circuit of psychotropic substances, consumption may be underreported.

5. Consumption based on statistical data sampling and distribution from retail outlets to the final user

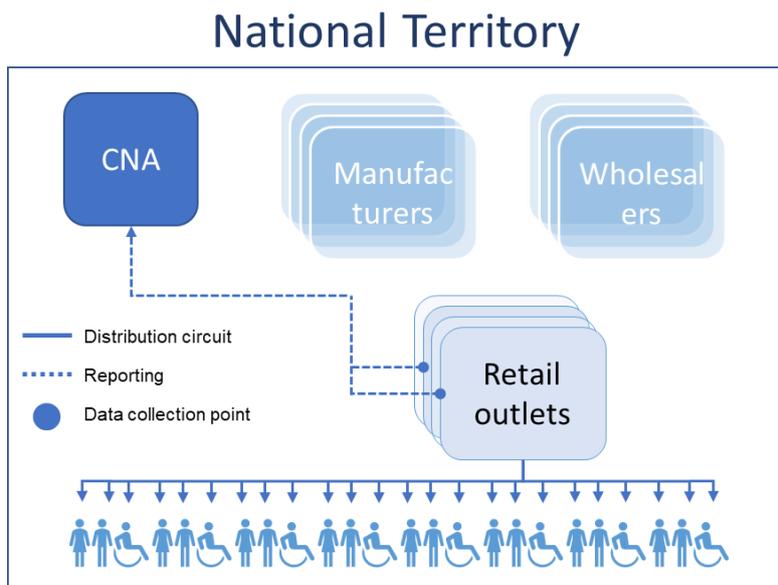
Characteristics of national market/distribution circuit

67. This methodology is similar to the one based on distribution from retail outlets to final users, but instead of data being collected from all entry points at the national or territory level, observations are derived from representative samples. The values obtained from this reduced group of data collection points (proxies) are used to extrapolate the consumption level of the entire population (see figure VIII).

68. Proxy retail outlets are a good way to reduce the amount of data collected and to simplify the collection process and information analysis. The selection of those proxies should be based on a clear understanding of the distribution capacity of the retail outlets within the country or territory. For example, if the distributors selected are located only in large cities, possibly because it is easier to gain access to that information, it may distort the data on consumption in rural areas.

69. A sound understanding of the demographics of the reporting country or territory can also play an important role in the selection of the most appropriate data collection points. Likewise, this knowledge should support the statistical mechanism implemented to extrapolate consumption data at the national level. For example, if two retail outlets (e.g., pharmacies) provide services in areas with similar population densities and socioeconomic profiles, it would be safe to assume that their consumption profiles are similar.

Figure VIII. Consumption based on distribution from proxy retail outlets to the final user



Advantages

70. A limited number of observation points will reduce the amount of data to be collected, processed and stored. This is particularly relevant when the number of retail outlets is very high, and if the figures extrapolated from the data sample provide a fair representation of the consumption level of the entire country or territory. The advantages of this method include the following:

- (a) *Reduced number of data collection points.* In comparison with the methodology based on distribution from retail outlets to final users (without sampling), this approach simplifies the reporting process, as the amount of data gathered and processed is only a subset of the statistical population;
- (b) *Balance of cost versus accuracy.* If the number of retail outlets turns the data collection process into a cumbersome and costly procedure, this methodology can reduce complexity without having an impact on the quality of the data.

Challenges

71. The following challenges have been identified:

- (a) The type of sampling used to select the data collection points (i.e., proxy retail outlets) will have an impact on the accuracy of the consumption data extrapolated from the sample. Examples include aleatory sampling, discretionary sampling (based on selected variables, such as location, distribution volume or hierarchy in the health system) and rotational sampling;
- (b) Sound statistical analysis is required in order to obtain a representative consumption data sample from which the consumption level at the country or territory level can be extrapolated;
- (c) Quantities of psychotropic substances included in exempted preparations (medicines) may be difficult to record. If the health information system excludes exempted preparations from the distribution circuit of psychotropic substances, consumption may be underreported.

IV. Validating consumption data

72. Validation is defined as the process of supporting or corroborating – on a sound basis – a fact, idea, action, etc. Data validation is an important step in improving the accuracy and quality of data sources and consequently of the data themselves. The inclusion of a validation process in the reporting exercise is intended to enhance the accuracy and completeness of the reported data and, ultimately, the reported levels of consumption of psychotropic substances. By comparing figures obtained from different sources or at different points in the data collection process, the reporting authority is more likely to find inconsistencies in the figures. Once the nature of the discrepancies is revealed, it is possible to take corrective or preventive measures to improve the quality of the data, that is, to obtain a better understanding of the quantities of psychotropic substances consumed within the country or territory.

73. The complexity and variety of validation mechanisms will be determined by the resources a competent national authority has at its disposal, including staff, its own data processing system and its

access to nationwide health or customs information systems and comprehensive data sets from reporting operators. More resources mean that more validation mechanisms can be implemented and a more elaborate validation process can be developed. A balance should be achieved between improving the quality of the data and the resources invested in the validation process.

A. Validation mechanisms

74. The present section contains various validation mechanisms that competent national authorities have highlighted as useful in finding gaps and inconsistencies in the consumption data furnished by reporting operators. At the same time, it is important to note that there is no one-size-fits-all approach to validating consumption data. Validation mechanisms may need to be adapted to suit local regulations or combined to increase the accuracy of the data collected.

1. Reported imports versus authorized/endorsed imports

75. Several competent national authorities use the imports-only or the calculated consumption methodology (see chap. III) to measure consumption levels. In such cases, an accurate measurement of the psychotropic substances imported by a country or territory is critical.

76. Three different data sources to measure imported quantities have been identified: (a) import authorizations issued by the competent national authority, including endorsements; (b) imports reported by licensed operators; and (c) imports reported by the customs office of the country or territory.

77. Some competent national authorities may be able to access data from all three sources, for example if the reporting authority has access to the customs information system of its own country and reporting operators diligently submit consumption data. On the other hand, some may find it challenging to gain access to information from any of those sources, for example if the authority in charge of statistical reporting to INCB is different to the one in charge of issuing import authorizations for psychotropic substances. Regardless of the number of data sources used in the validation process, closing gaps in the quantities reported as imports should lead to a more accurate measurement of consumption levels.

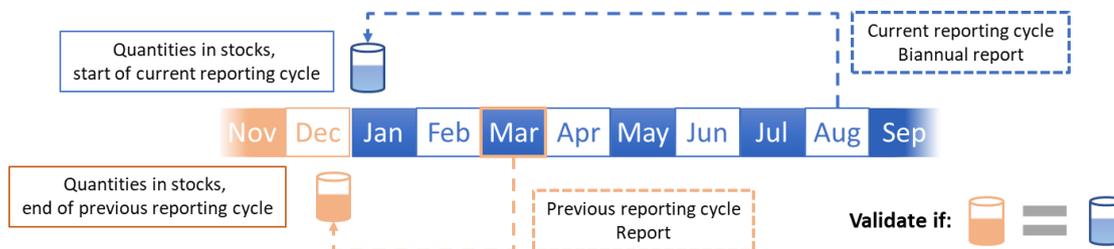
2. Reported inventories

78. As part of their reporting obligations, licensed operators (i.e., manufacturers, wholesalers, retailers, hospitals, pharmacies, etc.) usually report stock levels at the start and at the end of the reporting cycle. There should not be any variation in inventory levels if there are no gaps between consecutive reporting periods; for example, psychotropic substances in stock on 31 December of a particular year and on 1 January of the following year should be the same.

79. However, some reporting operators may find it challenging to keep their inventory books up to date at all times and may need to validate their inventories retroactively. For example, a manufacturer might report the quantities of psychotropic substances held in stock at the end of the previous reporting period (i.e., inventory as at 31 December) in March. The same manufacturer might furnish its biannual report in August, including the quantities of psychotropic substances held in stock at the beginning of the reporting period (i.e., inventory as at 1 January). The inventory levels in the two reports should not differ; however, there have been cases in which a simple validation process revealed evidence of the opposite.

80. Figure IX depicts the relationship between stock levels from one reporting cycle to the next and between two reports at different points in time.

Figure IX. Reported stocks between reporting cycles



81. Inventory at the beginning and at the end of a reporting period is a key element in the formula used to calculate consumption levels (see chap. III). Any inconsistencies in inventory levels should be addressed and clarified before they can be incorporated in the formula, otherwise the resulting figures on the consumption of psychotropic substances will be inaccurate.

3. Domestic trade

82. Domestic trade in psychotropic substances under international control among wholesalers and manufacturers is a common practice, especially in countries with a large manufacturing industry. Although the idea that a psychotropic substance is “consumed” when it is distributed from a wholesaler or manufacturer to a retail outlet is widely accepted, it is advisable to validate domestic trade among wholesalers and manufacturers in order to improve the reliability of the data reported.

83. For example, sales reported by one manufacturer should be reported as purchases by its trading counterparts. If that is not the case, it is necessary to examine the reason for the discrepancy. Should those sales have been reported as exports or losses? Are both parties to the transaction using the same anhydrous base content of a specific medicine or preparation?

84. Answers to those questions may provide the competent national authorities with solid evidence to determine whether its reporting operators have a strong and reliable reporting system in place. If the data are inaccurate or incomplete, other reporting obligations (i.e., those more directly related to measuring consumption levels) may be implemented using the same flawed system.

85. An additional benefit of validating domestic trade among wholesalers and manufacturers is the possibility of detecting attempts at diversion within the country or territory, for example if the sales reported by a manufacturer are higher than the quantities reported by its trading counterpart with no evident reason that explains the difference.

4. Psychotropic substances used in the manufacture of preparations or other substances

86. As defined in article 1 of the 1971 Convention, the term “manufacture” refers to “all processes by which psychotropic substances may be obtained, [including] refining as well as the transformation of psychotropic substances into other psychotropic substances. The term also includes the making of preparations other than those made on prescription in pharmacies.”

87. In addition, the term “preparation” is defined in the Convention as “any solution or mixture, in whatever physical state, containing one or more psychotropic substances”, or “one or more psychotropic substances in dosage form”.

88. Losses are inherent to the industrial process by which a psychotropic substance is manufactured or transformed into a preparation. Although losses are ideally marginal when compared with the quantities manufactured or used in preparations, it is important to validate the amounts of psychotropic substances lost in the manufacturing process when calculating consumption levels; otherwise, reporting authorities may end up furnishing values that exceed actual consumption.

89. The quantities of psychotropic substances used in the manufacture of non-psychotropic substances or exempted preparations (as defined in art. 3 of the 1971 Convention) should also be validated with the reporting operators. A non-psychotropic substance cannot be regarded as consumed in the light of the reporting obligations to INCB, as those substances are not under international control. In addition, exempted preparations may or may not be considered part of the reporting obligations related to consumption. A clear understanding of which set of substances and preparations are to be reported as consumed by the reporting operators is consequential in achieving reliable consumption figures.

5. Calculated consumption versus distribution from wholesalers and manufacturers to retail outlets

90. The calculated consumption methodology and the methodology based on distribution from wholesalers and manufacturers to retail outlets (see chap. III) are commonly used to gauge levels of consumption of psychotropic substances. Both methodologies rely heavily on data collected from reporting operators, including stocks, imports, exports and quantities manufactured and/or distributed to local operators.

91. In principle, the calculated methodology uses a formula to indirectly estimate the quantities of psychotropic substances injected into the retail market. The approach based on distribution from wholesalers and manufacturers to retail outlets measures consumption levels on the basis of a single variable: the distribution of a psychotropic substance. Regardless of the methodology used to calculate consumption levels, the data collection point is the same, namely, reports furnished by wholesalers and manufacturers.

92. If a competent national authority has access to accurate, timely and comprehensive data sets from its reporting operators, it can validate consumption levels using both methodologies. If the data are inaccurate, it means that the figures are not trustworthy and any conclusions resulting from the validation process will be flawed. If data are untimely, the figures may not be fit for purpose or may be imprecise. Finally, if the data set is incomplete, the formula used in the calculated consumption methodology may not consider all the variables, resulting in only partial consumption figures.

93. The simplicity of this validation mechanism lies in the fact that there is no need to change the data collection process; the data set collected from reporting operators simply needs to be extended to include all of the variables required to apply both methodologies. The reporting authority is likely to be in a position to use both data collection methodologies or to undertake minor changes in its data collection process in order to do so, thus making it possible to validate the consumption figures resulting from both exercises.

6. Third-party data sources

94. Research and academic institutions, national or regional statistical agencies (either private or governmental) and national or international organizations can be reliable alternative sources of information to validate consumption data. The data collected by those organizations can vary in nature and scope, making it particularly important to select the right data source. Given the relevance of public health information to Governments, it is likely that some type of data related to the consumption of medicines is already available.

95. The possible data collection points of a third-party data source are likely to differ from those described in the distribution circuit of psychotropic substances (see figure II). Thus, a direct comparison between the quantities of psychotropic substances calculated as consumed would be inadequate. However, a reporting authority could compare the trend in the data collected from its reporting operators with the trend obtained from a third-party data source. If the figures show a different tendency over time, a review of the data collection process might be worthwhile. Three examples of third-party data sources are discussed below.

Nationwide or regional health-related databases

96. It is common that nationwide health-related databases containing drug consumption data and pharmacovigilance centres that store such data are under the operational supervision and administration of a State-run organization, usually as part of the health ministry, institute or agency or an equivalent institution. Organizations that collect and administer data related to pharmacies, pharmacotherapy or epidemiology may be also relevant.⁹

Surveys

97. Surveys are a long-established data collection technique and not a data source per se. However, they are well-known instruments to target data sources of specific interest. INCB regularly uses surveys as an easy-to-deploy mechanism to gather data from competent national authorities. In recent years, online surveys have become increasingly popular, as they are faster and less expensive to implement, can reach a broader range of participants and are easier to post-process than their traditional paper-based counterparts.

Health-care facility data collectors

98. Data collected at health-care facilities can be a significant and detailed source of information. As mentioned above, however, it is not always easy to reach such a level of granularity. Nevertheless, innovation and new technologies have made it more feasible than ever before to deploy cost-effective data collectors at the health-care facility level. For example, the Department of Essential Medicines and Health Products of WHO has developed the Essential Medicines and Health Products Price and Availability Monitoring Mobile Application,¹⁰ which professionals at health-care facilities can use to collect and analyse prices and availability data on 32 essential medicines.

⁹ A detailed list of nationwide drug consumption databases in 25 countries in Europe can be found in Pili Ferrer and others, "Sources of European drug consumption data at country level", *International Journal of Public Health*, vol. 59, No. 5 (May 2014).

¹⁰ See www.who.int/medicines/areas/policy/monitoring/MedMon_leaflet_Web.pdf.

V. Use of consumption data to analyse trends in consumption and assess the availability of psychotropic substances for medical purposes

99. The Commission on Narcotics Drugs and INCB have acknowledged the benefits of collecting and analysing data on the consumption of psychotropic substances under international control. Through different resolutions and communications, the Commission and the Board have invited competent national authorities to report consumption data on a voluntary basis. However, the benefits of analysing consumption data go far beyond complying with reporting obligations.

100. Health information systems that are more reliable, accessible, expedient and intelligent equip Governments with the tools to drive evidence-based policies supported by relevant data. Accurate data on the consumption of psychotropic substances can only add to the effort to build policies around well-grounded, factual evidence. For example, the analysis of trends in the use or misuse of specific medicines, patterns in the distribution of medicines or the correlation of consumption data with demographic information could support strategies that improve public health.

101. Moreover, there is no reason why such policies or strategies should stop at the national level. Regional cooperation and information-sharing are additional mechanisms that can augment the benefits of collecting and analysing data on the consumption of psychotropic substances. It has been noted that neighbouring countries in similar socioeconomic situations profit from those practices, as they can share success stories, challenges and lessons learned with each other. They can also agree on action points that can be implemented on a larger geographical scale.

VI. Reporting of consumption data to the Board

102. Countries use form P to report consumption within the framework of the annual statistics on the manufacture, trade and consumption of substances controlled under the 1971 Convention. Further details on reporting in general, as well as on reporting consumption data, can be found in the training material for competent national authorities, which is available on the INCB website.

103. The evaluation of drug consumption over time, nationally and internationally, is simplified by the use of a unified unit of measurement, namely, the defined daily dose (DDD), which describes the assumed average maintenance dose per day for a substance used on its main indication in adults.

104. The term “defined daily doses for statistical purposes (S-DDD)”, which has replaced the term “defined daily dose (DDD)” in INCB publications, is used by the Board as a technical unit of measurement for the purpose of statistical analysis and is not a recommended prescription dose. Its definition is not free of a certain degree of arbitrariness. Certain psychotropic substances may be used in certain countries for different treatments or in accordance with different medical practices, and therefore a different daily dose could be more appropriate. The indicated S-DDD should be considered approximate and subject to modifications if more precise information becomes available.

105. Availability levels of psychotropic substances in S-DDD are calculated by dividing the quantities reported as consumed in a given year by 365 days; the result is then divided by the population of the country (expressed in thousands of inhabitants during the year in question), and then by the defined daily dose of the psychotropic substance in question as defined in the INCB technical report on psychotropic substances, which is published annually on the INCB website.

106. All consumption values are expressed in defined daily doses for statistical purposes (S-DDD) per 1,000 inhabitants per day, abbreviated S-DDD_{pt} (where “pt” stands for “per thousand”).

VII. New technologies shaping the data collection process

107. The present document is not intended to be an exhaustive compilation of state-of-the-art techniques or technologies that could support the data collection process, but to highlight key elements that some international organizations advocate as important in the advancement of the digital transformation of health information systems.

108. The past few decades have been characterized as the information age, in which information technologies are pervasive in all areas of society. This reality has forced people to improve their ability to decide which information is important and necessary among all the information that is available. New technologies are paramount in delivering the right knowledge to the appropriate group of individuals within a public health organization, including practitioners, operators, managers and policymakers.

109. As technology has moved forward, health information systems have also become more advanced; among other things, they are faster, more robust, accessible and accurate, more data can be collected, stored, processed and analysed, more data collection sources can be integrated, and different data validation mechanisms can be implemented. Given the potential that new health information systems have to offer, the Board has noted how an increasing number of competent national authorities are able to collect consumption data closer to the final user within the psychotropic substances distribution circuit, including at the pharmacy, the practitioner or even the prescription level.

110. Advances in technology should support the transformation of data into information and then into relevant knowledge. In addition to measuring consumption levels closer to the final user, the shift from the traditional way of collecting and analysing data towards one that integrates new technologies could open up more possibilities.

111. For example, structured data (i.e., data organized in a well-defined and agreed format) are the cornerstone of traditional information systems. If each licensed operator fulfilled its reporting obligations using its own format, or no format at all (just randomly arranged numbers), it would be very difficult for a reporting authority to administer an information system based on the resulting data sets.

112. New technologies open up the possibility of collecting unstructured data and using them alongside traditional data sources. To borrow from the previous example, what if an information system had the ability to analyse and understand each reporting operator's format and present a comprehensive result to the competent national authority? Moreover, what if the same information system were able to analyse other sources of information – such as demographics, consumer price indices, treatment definitions and guidelines, digital prescription systems and even social media events – and to correlate all of that information and present an overview of the consumption levels in a country or territory and the impact it has on public health?

113. To achieve such a level of insight, it is necessary to equip health information systems with new technologies, such as big data analytics, machine learning algorithms and artificial intelligence. It is not enough to update the information technology infrastructure or develop new software to attain such results. Coordinated and nationwide policies must be considered in the areas of data governance, knowledge management and sharing, standards for quality and interoperability, and technology and innovation, to name but a few examples.