

GUIDELINES ON REPORTING ON LOSSES AND DESTRUCTIONS OF NARCOTIC DRUGS TO INCB

A. BACKGROUND

1. Article 20 of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, requires Parties to the Convention to annually furnish statistical returns¹ to the Board. No obligation to report to the Board on losses and destructions of narcotic drugs is included in this article. Nevertheless, since many years the Board has encouraged Governments to report, on a voluntary basis, manufacturing losses and destructions of narcotic drugs in Form C², in order to allow Governments to account completely for the disposal of amounts of narcotic drugs that were manufactured but are no longer available for medical or scientific uses.

2. The data furnished by Governments need to be comprehensive in order to allow the Board to adequately assess the quantities of narcotic drugs disposed of and the quantities of narcotic drugs available. However, information on losses and destructions of narcotic drugs reported by Governments to the Board indicated significant variations in their methods of data calculation and collection. The Board, therefore, decided to review the concept of reporting on losses and destructions and to elaborate guidelines that would facilitate comprehensive and comparable reporting by Governments.

3. In the process of review of the concept of reporting on losses and destructions, the Board collected information from Governments with experience in this field. In addition, the Board convened in May 2008 a working group of national experts, which examined the information collected by the Board and provided additional expertise and suggestions on the guidelines.

4. The below presented new concept of reporting on losses and destructions of narcotic drugs should be used when calculating data to be reported in the Annual Statistics of Production, Manufacture, Consumption, Stocks and Seizures of Narcotic Drugs (Form C), Part I. Column 6 (“Quantity lost or destroyed”). In order to support national drug control administrators to correctly use the new concept, the explanations provided below have been prepared for distribution to national competent authorities and for inclusion on the INCB website.

B. GUIDELINES

5. The Board invites Governments to report in the Annual Statistics of Production, Manufacture, Consumption, Stocks and Seizures of Narcotic Drugs (Form C), Part I. Column 6, information on losses and destructions of narcotic drugs, which occurred during the process of manufacture and wholesale distribution of these narcotic drugs. This information is important for the analysis by the

¹ Under article 20, Parties shall furnish statistical data on (a) production or manufacture of drugs; (b) utilization of drugs for the manufacture of other drugs, of preparations in Schedule III and of substances not covered by this Convention, and utilization of poppy straw for the manufacture of drugs; (c) consumption of drugs; (d) imports and exports of drugs and poppy straw; (e) seizures of drugs and disposal thereof; (f) stocks of drugs as at 31 December of the year to which the returns relate; and (g) ascertainable area of cultivation of the opium poppy. In addition Parties shall furnish data respecting drugs imported into or procured within the country or territory for special purposes, as well as quantities of drugs withdrawn from special stocks to meet the requirements of the civilian population.

² Annual Statistics of Production, Manufacture, Consumption, Stocks and Seizures of Narcotic Drugs.

Board of the statistics on the manufacture/production, consumption, utilization and stocks of narcotic drugs furnished by Governments, in order to determine whether there are any imbalances between the quantities of narcotic drugs reported as available in the country and the quantities reported as disposed of for legitimate purposes.

6. There are two primary categories of losses. Losses are either “recoverable” or “non recoverable.” Recoverable losses are tangible and thus are collected, quantified, held in stocks, reprocessed or destroyed through acceptable means (often incineration). Non recoverable losses can not be collected and quantified but may still be estimated.

7. Numerous steps involved in the manufacture of narcotic drugs and the preparations derived from them produce recoverable and non recoverable losses. Losses and destructions may be classified into four categories: (i) technological or process related losses and/or destructions; (ii) quality control/assurance related losses and/or destructions; (iii) thefts; and (iv) other losses and/or destructions. Details of manufacturing stages at which losses/destructions occur are provided below.

8. The quantity to be reported under Column 6 “Quantity lost or destroyed” should be the total quantity of a narcotic drug lost or destroyed in the country/territory during manufacture and wholesale distribution of that narcotic drug. It should include:

- (i) non recoverable process-related losses during purification, milling, transformation to salts, isomers, esters, ethers and during manufacture of preparations, such as overfill, wastestream and breakage;
- (ii) non recoverable other losses such as evaporation, leakage and accidents;
- (iii) destroyed narcotic drugs which may include collected waste and spillage, rejects due to expiry date or quality defects and quality assurance samples.

9. Thefts occurring at manufacturing and wholesale levels should also be reported under “Quantity lost or destroyed”. Explanations on significant thefts should be provided under “Remarks” on page 1 of the Form C.

10. The following quantities should not be reported under Column 6: (i) quantities lost as a result of the industrial yield of the transformation process of one narcotic drug into another narcotic drug or a substance not controlled under the 1961 Convention, and (ii) quantities lost during the manufacture of Schedule III preparations.

11. The following guidelines regarding losses and/or destruction of narcotic drugs should also be taken into consideration by Governments:

- (i) All narcotic drugs lost and destroyed must be documented in verifiable records.
- (ii) Quantities of recovered narcotic drugs should be reported as stocks until the time they are reprocessed or destroyed.
- (iii) Care should be taken to avoid double counting. For instance, in the case where narcotic drugs which were already accounted for as consumed in previous years are recalled to manufacturers or wholesalers from pharmacies, these should be reported as gains/acquisitions in Form C under “Remarks”. These quantities should be further reported either as destroyed or held in stock, as appropriate.

- (iv) Significant quantities of recoverable losses (i.e. wastes) are increasingly being exported from one country to another country for destruction. This is an acceptable and necessary business practice. The destruction should be reported to INCB by the importing country, where the destruction is performed, in the year in which it occurred. The exports of such wastes should not count against the importing countries' estimate for the narcotic drug in question. However, they should be covered by the appropriate import and export authorizations and reported in the respective Quarterly Statistics of Imports and Exports of Narcotic drugs (Form A), with the indication that these quantities refer to wastes to be destroyed.
- (v) Significant quantities of narcotic drugs are utilized for industrial research and development purposes. Quantities of narcotic drugs utilized for these purposes should be reported as losses and/or destructions, as appropriate. The quantities of narcotic drugs, which are used for scientific purposes in clinical trials, should be reported in Form C, Part I, under Column 2 ("Quantity consumed").

C. MANUFACTURING STAGES DURING WHICH LOSSES AND/OR DESTRUCTIONS OCCUR

I. Raw materials

- A. Technological and Process related losses and/or destructions
- Purification (Refining)
 - Transformation into/from bases, acids, salts, isomers, esters, ethers
 - Isomeric separation
 - Micronization
 - Drying
 - Milling
 - Sieving
 - Weighing, packaging, labelling
- B. Quality Control/Assurance related losses and/or destructions
- Sampling (in-coming material, in-process samples, finished material, stability samples, retains³, validation)
 - Quality defects
- C. Thefts
- D. Other losses and/or destructions
- Chemical decomposition
 - Leakage during storage
 - Evaporation during storage
 - Accidents
 - Expired materials
 - Equipment malfunction

³ Representative samples of raw materials, intermediates, finished preparations etc, which are held for the purpose of enabling the conduct of further evaluations and investigations, for example in the event of a complaint or a query relating to these materials.

II. Preparations (including process intermediates such as powder mixtures, beads)

- A. Technological and Process related losses and/or destructions
 - All stages of transformation into preparations (tableting, encapsulating, filling of injectables, bottling, patch manufacturing, sterilization, etc.)
 - Weighing, packaging, labelling
- B. Quality Control/Assurance processes
 - Sampling (in-coming material, in-process samples, finished preparations, stability samples, retains, validation)
 - Quality defects
- C. Thefts
- D. Other losses and/or destructions
 - Chemical decomposition
 - Accidents
 - Expired preparations
 - Equipment malfunction

III. Industrial Research and Development

- Pilot batches
- Experimental batches
- Developmental batches
- Scale up batches
- Validation
- Other research purposes