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Implementation of the international drug control treaties

Proposal concerning quality evaluation of the performance of drug analysis laboratories

Report of the Executive Director

Summary

The present report has been prepared pursuant to Commission on Narcotic Drugs resolution 52/7, entitled "Proposal concerning quality evaluation of the performance of drug analysis laboratories". It presents a summary of the work undertaken by the United Nations Office on Drugs and Crime in areas covered by the resolution, in particular in engaging with Member States on the provision of quality assurance support to forensic laboratories. The report reflects on issues related to quality evaluation of the performance of drug-testing laboratories for further consideration and consultation by Member States and provides recommendations for future action.

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I. Introduction

1. In its resolution 52/7, entitled "Proposal concerning quality evaluation of the performance of drug analysis laboratories", the Commission on Narcotic Drugs recalled General Assembly resolution 49/168, section II, and General Assembly resolution 52/92, section II, in which the Assembly requested the United Nations International Drug Control Programme, now called the United Nations Office on Drugs and Crime (UNODC), to continue providing assistance to Member States requesting support in establishing or strengthening national drug detection laboratories; and also recalled Economic and Social Council resolution 2003/32, in which the Council urged relevant international organizations, in consultation with UNODC, to provide financing and other support for training of experts in various subjects related to the fight against the world drug problem, with particular emphasis on, inter alia, drug-testing laboratories and laboratory quality assurance.

2. Also in resolution 52/7, the Commission, recognizing the cost-effectiveness of having a sustainable international network of laboratories and scientific support services, called upon Member States and subregional, regional and international entities to contribute, in all areas within their purview, to the work of UNODC set out in the resolution, in particular by exploring innovative ways to ensure the more effective exchange of expertise and information worldwide. That would reduce gaps between Member States and facilitate standardization of approaches and international cooperation.

3. In this context, and in accordance with its resolution 50/4, entitled "Improving the quality and performance of drug analysis laboratories", the Commission on Narcotic Drugs acknowledged and re-emphasized in resolution 52/7 the added value of the support of UNODC on international quality assurance issues, in particular through the international collaborative exercises, a proficiency-testing scheme for drug-testing laboratories.

4. Directly related to the international collaborative exercises is the provision to Member States of analytical reference standards for controlled drugs, supported by the regular budget, in order to facilitate the analytical work of national laboratories.

5. Recognizing that, in view of the expected increase in the number of participating laboratories, the continuation of UNODC support for drug-testing laboratories has significant financial implications, the Commission requested in the same resolution that such services be provided at a reasonable cost to Member States in order to ensure, to the extent possible, the sustainability and self-sufficiency of the quality assurance programme.

6. The present report summarizes the work undertaken by UNODC in areas covered by the resolution, in particular in engaging with Member States on the provision of quality assurance support to forensic laboratories. It provides recommendations for future action for further consideration by Member States. The report also summarizes the outcome of informal consultations with the standing panel of forensic experts related to the invitation of the Commission to Member States to consider a certification process for laboratories, coordinated by UNODC through its quality assurance programme. Summary reports on the implementation of individual rounds of the international collaborative exercises and a 10-year review are available separately.

II. Implementation of Commission on Narcotic Drugs resolution 52/7

A. Introduction to the international collaborative exercises portal and comprehensive quality assurance support

7. Pursuant to Commission on Narcotic Drugs resolution 52/7, UNODC explored and put in place mechanisms to extend the international collaborative exercises to more drug-testing laboratories, with particular attention to cost-effectiveness and the reduced regular budget support for the exercises.

8. The international collaborative exercises provide the means for:

(a) Laboratories to continuously monitor their performance through a confidential evaluation of their laboratory results, an important element for the implementation of quality management systems;

(b) Assessing performance on a global basis, as the programme attracts the participation of laboratories from both States with adequate resources and those in need of assistance;

(c) An evidence-based approach to tailoring technical support and assistance provided to laboratories following the identification of factors affecting laboratory performance and development.

The implementation of the programme is overseen by a standing panel of forensic experts, which provides consultations and advice on quality and forensic issues.

9. The international collaborative exercises have been operating on a nearly continuous basis since their introduction in 1995. They currently assess biannually the ability of drug-testing laboratories to identify and quantify drugs of abuse in seized samples and in biological fluids. To date, more than 90 laboratories from over 40 Member States have participated in the exercises.

10. The implementation of the international collaborative exercises is supported by the United Nations regular budget. Although the programme has experienced growth of over 30 per cent in terms of participating laboratories, the level of funding has stagnated, notwithstanding inflation and increased operating costs. This has implications for the sustainability of the exercises, particularly in view of the expected increase in participation resulting from the implementation of the resolution.

11. Using general purpose funds, UNODC developed a web-based portal with enhanced security features for the international collaborative exercises, which was piloted in the second half of 2009. The portal, known as e-ICE, makes it possible for participating laboratories to register for the programme on the Internet.

12. Currently, the portal supports about 60 participating laboratories from 34 Member States. The improved and efficient service provided to participating laboratories includes personalized, confidential evaluation reports within minutes of the submission of the analytical results. The portal also serves as a repository of all information and resources related to the programme.

13. Taking into consideration the concerns raised by the Commission in resolution 52/7 regarding the differences among Member States in terms of the technical level of their scientific and laboratory services, and following its recommendations, UNODC has been reinforcing its quality assurance programme and has continued to provide participating laboratories with essential resources. These include drug reference standards, recommended methods of analysis and guidelines on quality assurance, drug analysis and forensic best practices.

14. Accurate forensic data are important for an effective drug control system. UNODC manuals and guidelines assist drug analysis and forensic laboratories worldwide to operate to internationally accepted standards, introduce and implement quality management systems in the laboratory and contribute to the promotion and harmonization of quality standards throughout the world. Electronic versions of manuals and guidelines can be downloaded directly from the UNODC website.

B. Evaluation of the performance of laboratories

15. In consultation with the standing panel of forensic experts, which oversees the implementation of the international quality assurance programme, UNODC considered the possible implications of a certification process for laboratories participating in the programme. The outcome of these consultations is outlined below.

16. The international collaborative exercises are part of the UNODC quality assurance programme. They primarily support the continuous improvement of participating laboratories and are not aimed at certifying the competence of laboratories. In that context, the following elements should be noted:

(a) UNODC can certify only a laboratory's participation in the international collaborative exercises;

(b) The issuance of a certificate should not be taken as recognition by UNODC that the participating laboratory is competent in drug analysis, although a participating laboratory's lack of a certificate does raise questions about its competence;

(c) In order to encourage continued participation in the international collaborative exercises and to maintain confidentiality, which are two essential elements of the programme, certificates should be issued only to participating laboratories, not to their controlling organization or government;

(d) Certification of participation in the programme without reference to the performance of a laboratory would serve only as an indication of its regularity of participation, and thus its awareness of and interest in quality issues;

(e) Certification with full details of the evaluation of analytical results (for example, numbers of correct results, false positives, false negatives, samples not tested) for each exercise would be an overly complicated process and would not necessarily benefit participants that do not succeed in complying with the requirements of the exercises;

(f) Certification of satisfactory completion is possible only when it is limited to specific exercises and when it clearly relates only to qualitative

requirements of the international collaborative exercises as currently implemented and to the identification of a limited list of specified drugs;

(g) Certificates could be issued after each round of the international collaborative exercises (usually two rounds per year are implemented) or annually.

C. Reference standards for drug analysis

17. In the framework of the international collaborative exercises, and also for the routine analytical work and operations of national drug-testing laboratories, UNODC provides standards and reference samples for drugs under international control, their metabolites and precursors, as well as selected impurities and related substances found in illicitly manufactured drugs, for comparative analytical purposes.

18. In its resolution 50/4 the Commission on Narcotic Drugs recognized the importance of the support provided by UNODC and called for continued support for the analytical work of laboratories through the provision of reference samples of controlled substances. Supported by regular budget resources, these services are currently provided free of charge to Member States. While the demand for reference standards has increased, financial support has remained static, and has effectively decreased owing to inflation and related costs for the maintenance of a central source of reference standards and samples for distribution to national laboratories.

19. UNODC welcomes the proposal of the Commission in its resolution that such services should be provided at a reasonable cost to Member States in order to ensure, to the extent possible, the sustainability and self-sufficiency of the quality assurance programme. Suitable costing matrices are being considered by UNODC in support of the resolution and to ensure that the benefits of quality assurance support for Member States are not diminished.

D. Import and export authorization for substances under international control

20. The procurement of reference standards for narcotic drugs, psychotropic substances and precursors for analytical purposes may sometimes be plagued with difficulties. Obstacles may arise owing to inadequate awareness of procedural requirements for issuing import authorization, national legislation or other regulations on importation of controlled substances, or a lack of appropriate infrastructure for the shipment of controlled substances into or out of a country. In particular, the procedure for export certificates accompanying the test samples for the international collaborative exercises programme can jeopardize the confidentiality of information about controlled substances in the test samples. This is a significant, ongoing hindrance to the administration of the international

collaborative exercises, which has been further complicated by procedures resulting in additional costs for national laboratories and UNODC.[1]

21. A broader implementation of the guidelines by Member States would help to optimize regulatory procedures and facilitate the work of national laboratories and research institutes. In addition, it would ensure smooth implementation of the UNODC quality assurance programme and enable the immediate provision of the support required by laboratories to meet internationally recognized standards of performance. Finally, it would facilitate their participation in the international collaborative exercises programme, while at the same time reinforcing and ensuring the confidentiality of analytical results.

E. Sustainability of the quality assurance programme and financial implications

22. As indicated in the financial statement on resolution 52/7,[2] its implementation has resource implications in terms of extrabudgetary funding related to:

(a) The optimization of current workflows and automation and computerization of existing manual procedures associated with the international collaborative exercises to increase capacity and support more laboratories;

(b) The administration of the exercises, including the issuance of import and export authorizations for reference and test samples and related supplies and materials;

(c) The upgrade of the status of the UNODC laboratory to that of a proficiency test provider and the preparation and distribution of test samples within the provisions of the programme;

(d) Support for the initial purchase of samples of controlled substances and certified reference standards.

III. Conclusions and recommendations

23. The provisions of resolution 52/7 reflect the recognition by Member States of the important role of laboratories as part of the national drug control system and the value of laboratory results and data to criminal justice systems, law enforcement agencies, health authorities and policymakers.

24. National laboratories worldwide need to carry out their analytical work by conforming to the requirements of an international quality standard. Pursuant to Commission on Narcotic Drugs resolution 50/4, as re-emphasized in its resolution 52/7, UNODC has continued the implementation of its quality assurance

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[1] See International Narcotics Control Board, *Guidelines for the import and export of drug and precursor reference standards for use by national drug testing laboratories and competent national authorities* (United Nations publication, Sales No. Mult.08.XI.6).

[2] *Official Records of the Economic and Social Council*, *2009*, *Supplement No. 8* (E/2009/28–E/CN.7/2009/12), annex VIII.

programme with the aim of improving the performance of laboratories to meet internationally accepted standards.

25. It is recommended that Member States encourage the participation of forensic laboratories in proficiency testing schemes, including but not limited to the UNODC international collaborative exercises, as a commitment to quality and continuous improvement. In addition, Member States are requested to provide the financial and material support requested by national drug-testing laboratories to participate in such schemes.

26. Member States should review, in consultation with UNODC and other relevant bodies, as required, the reporting mechanism on the evaluation of laboratories' performance within the UNODC quality assurance programme, considering the implications of a certification process (see sect. II.B above) that might have a negative effect on the programme's fulfilment of its commitment to quality and continuous improvement.

27. Member States are invited to consider an alignment of national legislation governing import and export authorizations for controlled substances for the purposes of proficiency testing with the guidelines developed by the International Narcotics Control Board, where possible, so as to facilitate the smooth and uninterrupted participation of their drug-testing laboratories in relevant performance evaluation exercises such as the UNODC international collaborative exercises.