TOBACCO PRODUCT REGULATION

Building laboratory testing capacity

World Health Organization

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Tobacco product regulation: building laboratory testing capacity.

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PREFACE

It is well established that tobacco use is a major public health problem. However, tobacco products are one of the few openly available consumer products that are virtually unregulated in terms of contents, design features and emissions. The majority of countries hesitate to implement regulations in this area, partly due to the technical complexity associated with tobacco product regulation. There has been a high demand from WHO Member States for resources consolidating information on tobacco testing and building laboratory capacity for countries, especially to facilitate the implementation of Articles 9 and 10 of the WHO FCTC[1]. This is to provide a useful, comprehensible and easy guide for regulators and policymakers on how to test tobacco products, what products to test, and how to use testing data in a meaningful way to support regulation.

The importance of laboratory testing is reflected in the WHO Framework Convention on Tobacco Control (WHO FCTC). Article 9 of the WHO FCTC defines obligations for Parties with respect to the testing of tobacco products, while Article 10 deals with the disclosure of information on the contents and emissions of tobacco products. The disclosure of product information takes two forms: 1) the disclosure of information by manufacturers to regulators, and 2) the disclosure of information from regulators to the public. Tobacco product testing is used to generate data necessary to support both forms of disclosure.

In 2006, the first Conference of the Parties (COP) to the WHO FCTC established a working group to elaborate guidelines and recommendations for the implementation of Articles 9 and 10 of the Treaty (Decision FCTC/COP1(15)). COP 2 extended the mandate of the working group and encouraged WHO's Tobacco Free Initiative (WHO TFI) to continue its work on tobacco product regulation (Decision FCTC/COP2(14)). In 2010, the partial guidelines submitted at COP4 were adopted. The partial guidelines currently contain recommendations for regulation to reduce the attractiveness of tobacco products. Recommendations to reduce the addictiveness and toxicity of tobacco products will be developed later. The working group was requested by the COP to continue its work to elaborate the guidelines in a step-by-step process, with updates on addictiveness and toxicity requested to be submitted to future sessions of the COP for consideration.

It is important to note that, contrary to claims by the tobacco industry, these guidelines are final and in effect. The regulatory measures advocated by the partial guidelines are to be treated as minimum requirements and do not prevent Parties from adopting more comprehensive measures.

[1] Participants of a WHO workshop on the How-to's of Establishing a Testing Laboratory in (April 2016, New Delhi, India) requested WHO to prepare a handbook on building laboratory capacity. Additionally, the WHO Tobacco Laboratory Network's sixth meeting (Maastricht, Netherlands, 9-11 May 2016) recommended the development of a primer informing governments and the public of WHO TobLabNet's activities in order to expand membership and build testing capacity globally.

WHO has continually supported Member States in developing laboratory capacity. In 2004, WHO TFI published a recommendation from the WHO Study Group on Tobacco Product Regulation (TobReg) on 'guiding principles to increase laboratory capacity to facilitate the implementation of Articles 9 and 10 of the WHO FCTC and to guide the initiation of tobacco product testing'. *(1)* The guiding principles provided advice to countries intending to develop such capacity and help in realising this objective. Over the intervening years, new knowledge has developed and progress has been made to support these efforts; these include establishing the WHO Tobacco Laboratory Network (TobLabNet) in 2005 and the Global Tobacco Regulators Forum (GTRF) in 2016. Therefore, it is appropriate to update the previous document and provide a practical guide for countries interested in developing or accessing tobacco product testing capacity to support their regulatory authority.

This document provides options for building laboratory capacity, which include developing a testing laboratory, using an existing internal laboratory, contracting an external laboratory, and making use of the support mechanisms available, including but not restricted to WHO TobLabNet. Finally, it provides practical, step-by-step approaches to implementing tobacco testing and is relevant even to countries with inadequate resources to establish a testing facility.

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GLOSSARY

Accreditation — the documentation by an independent body that a laboratory has the systems in place that should enable them to produce reliable results that have been adequately tracked and verified.

Accuracy — the nearness of a measurement of a quantity to the quantity's true value

CDC — U.S. Centers for Disease Control and Prevention

DAD — diode array detector

FID — flame ionization detection

Firewall — a system to ensure that data and information are protected so that public health and commercial interests are separate and not accessible to each other

GC — gas chromatography

HPLC — high-performance liquid chromatography

Labstat — a private commercial tobacco analysis laboratory, Labstat Incorporated, in Kitchener, Ontario, Canada

LC — liquid chromatography

MS — mass spectrometry

MS/MS — tandem mass spectrometry

Precision — a determination of how close measurement results are to each other if a measurement is made repeatedly on the same sample, typically using the same method

Quality control — a process which evaluates whether systems are operating within standard parameters on an ongoing basis

Ruggedness — ability of an analytical system to withstand deviations from the defined analytical method.

Selectivity — the ability to correctly identify that a substance is not present when it is indeed not present.

Sensitivity — the ability of a measurement to make accurate and precise determinations at low levels.

TCD — thermal conductivity detector

TFI — Tobacco Free Initiative of the World Health Organization

TobLabNet — WHO Tobacco Laboratory Network

TobReg — WHO Study Group on Tobacco Product Regulation

TSNAs — tobacco-specific nitrosamines