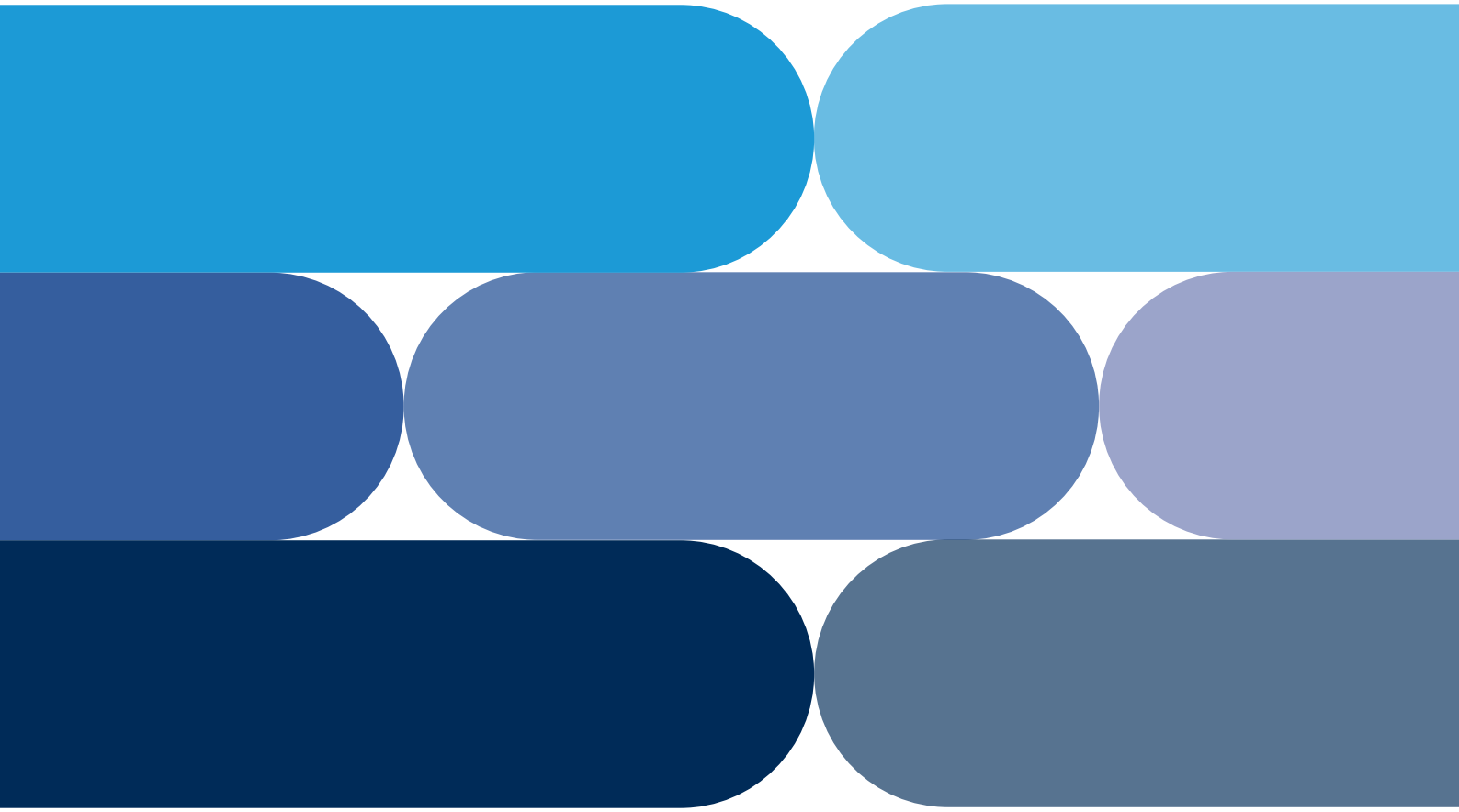
WHO Global Benchmarking Tool (GBT)

for Evaluation of National Regulatory System of Medical Products

Revision VI



World Health Organization

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Contents

Introduction

The World Health Organization (WHO) considers medical products and other health technologies one of the six building blocks of health systems. Unlike many other commodities, however, end users and health care workers are typically not in a position to judge the quality of medical products. It is therefore essential that the interests and safety of the public be entrusted to a regulatory body responsible for ensuring the quality, safety, and efficacy of medical products throughout the product life cycle.

Regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective, efficient and transparent regulatory systems are consequently an essential component of overall health systems and contribute to desired public health outcomes and to innovation and investment. In contrast, inefficient regulatory systems can be a barrier to access of safe, effective and quality medical products.

WHO has played a pivotal role in supporting countries to strengthen their regulatory systems, a role implicitly mandated by the WHO constitution and elaborated explicitly in various World Health Assembly (WHA) resolutions. Most notable of these is Resolution WHA 67.20 that addresses strengthening regulatory systems for medical products adopted in May 2014 .

The benchmarking of regulatory systems referred to in Resolution WHA 67.20 implies a structured and documented process by which Member States (MSs) can identify and address gaps with the goal of reaching a level of regulatory oversight commensurate with a stable, well-functioning and integrated regulatory system.

The use of the WHO global benchmarking tool (GBT) is the primary means by which WHO assesses regulatory systems for the regulation of medical products. The tool and benchmarking methodology enable WHO and regulatory authorities to identify areas of strength as well as areas for improvement; facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address identified gaps; to aid in the prioritization of investments in IDP implementation; and to help monitor progress.

WHO began assessing regulatory systems in 1997 using a set of indicators designed to assess the regulatory program for vaccines. Since that time, several tools and revisions have been introduced, and the regulatory systems of over 150 countries have been benchmarked.

The development of a unified WHO GBT for the assessment of medicine and vaccine programmes began in 2013 following a mapping of benchmarking tools internal and external to WHO with a view to ensuring policy coherence, maximizing regulatory outcomes and reducing burden on regulatory authorities.

The benchmarking policy and methodology were the subject of two international consultations in January and December 2015, respectively. The GBT revision VI was also the subject of a public consultation and extensive expert consultation in 2018. Importantly, GBT revision VI was integrated with the medical regulatory systems assessment tools developed by the WHO Regional Office for the Americas/Pan American Health Organization (AMR/PAHO).

The GBT replaces all tools previously used by WHO, representing the first truly ‘global’ tool for benchmarking regulatory systems. The GBT is designed to evaluate the overarching regulatory framework and the component regulatory functions e.g. clinical trial oversight through a series of sub-indicators that may also be grouped and examined according to nine cross-cutting categories or themes, for example, quality and risk management system. Fact sheets have been developed for each sub-indicator to guide the benchmarking team and ensure consistency in the evaluation, documentation and rating of the sub-indicator.

The GBT also incorporates the concept of ‘maturity level’ or ML (adapted from ISO 9004), allowing WHO and regulatory authorities to assess the overall ‘maturity’ of the regulatory system on a scale of 1 (existence of some elements of regulatory system) to 4 (operating at advanced level of performance and continuous improvement).

A benchmarking manual is available to help users to understand and apply the policy, methodology and process to be followed and completed for benchmarking of regulatory system of medical products.

The GBT revision VI (for medicines and vaccines) is available in four UN official languages of English, French, Spanish and Russian.

The GBT is supported by a computerized platform to facilitate the benchmarking, including the calculation of maturity levels. The computerized GBT (cGBT) is available, upon request, to Member States and organizations working with WHO under the Coalition of Interested Parties (CIP).

All queries related to GBT should be sent to WHO Regulatory Systems Strengthening Team at nra_admin@who.int.

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