



# **DELIVERING QUALITY-ASSURED MEDICAL PRODUCTS FOR ALL**

**2019–2023**



WHO's five-year plan to help build  
effective and efficient regulatory systems



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# Foreword

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People who work in health care expect the products they use to work as described on the box – in fact, to actually be what is described on the box. The fundamental issue is trust: just as patients need to be able to trust in our expertise, health workers need to be able to trust that products they prescribe actually do what they are meant to do: prevent illness and improve people's health.

That, in essence, is what we aim for in this five-year plan, in a context of increasing globalization, technological advance, changing disease patterns and demographics, and the disturbing prevalence of substandard and falsified products.

Good regulatory systems, providing oversight of health products throughout their life-cycle from the laboratory to the health facility, are the linchpin of quality prevention, diagnosis and treatment. They are an essential part of WHO's drive towards universal health coverage (UHC) and a key contribution to reaching the "triple billion" target (1 billion more people benefiting from universal health coverage, 1 billion more people better protected from health emergencies and 1 billion more people enjoying better health and well-being) set by WHO's 13th General Programme of Work.

Our record in this area speaks for itself. There are many achievements to point to, but the one that stands out for me is a national success story. With WHO's robust guidance based on assessment made by our Global Benchmarking Tool, the United Republic of Tanzania has become the first country in Africa to achieve a well-functioning regulatory system for medical products. I congratulate Tanzania and our Tanzanian colleagues, and look forward to many more countries' commitment to achieving this status over the next five years.

Another source of pride is the quiet but steady work of the WHO Prequalification Programme. Over the years, it has contributed to treating millions of people with quality, cost-effective medicines, including HIV treatments, as well as to protecting millions of children worldwide from vaccine-preventable diseases through safe, effective and quality vaccines. The same goes for our core function of setting global standards for medical products, which continues to ensure that manufacturers and regulators have clear norms to adhere to and a global point of reference. This is particularly important in an increasingly globalized world, where medical products are sourced from different countries with sometimes differing regulatory standards and requirements.

Rather than simply wringing our hands about this challenge, WHO is leveraging globalization in a positive way. Partnering with regional and national networks all over the world, we promote a collaborative reliance model for regulatory authorities. Collaboration helps such authorities to cut costs and reduce the time it takes to get sorely needed medical products to patients; reliance allows the expertise and experience of trusted national regulators to be shared and their benefits amplified.

This is the ethos and approach of our five-year plan. With its four strategic priorities for regulatory support, it is ambitious but feasible.

I have great confidence in the enthusiasm and abilities of my colleagues at WHO, the energy and receptiveness of the national regulatory authorities we work with, and the diverse ways in which our international partners support us. With their cooperation and a clear plan to work from, I look forward to the next five years.

**Dr Mariângela SIMÃO**

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Access to Medicines, Vaccines and  
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Geneva, 2019



# Abbreviations

<b>ADRs</b>	Adverse Drug Reactions	<b>IDP</b>	Institutional Development Plan
<b>AEFI</b>	Adverse Events Following Immunization	<b>IGAD</b>	Intergovernmental Authority on Development
<b>AEIVD</b>	Adverse Events related to IVDs	<b>IMDRF</b>	International Medical Device Regulators Forum
<b>AEMD</b>	Adverse Events related to Medical Devices	<b>IPRP</b>	International Pharmaceutical Regulators Programme
<b>AMRH</b>	African Medicines Regulatory Harmonization	<b>IVDs</b>	In vitro diagnostics
<b>APEC</b>	Asia-Pacific Economic Cooperation	<b>KPI</b>	Key Performance Indicator
<b>API</b>	Active Pharmaceutical Ingredient	<b>LMICs</b>	Low- and Middle-Income Countries
<b>ASEAN</b>	Association of Southeast Asian Nations	<b>ML3</b>	Maturity Level 3
<b>AVAREF</b>	African Vaccine Regulatory Forum	<b>MSM</b>	Member State Mechanism
<b>CARICOM</b>	Caribbean Community	<b>NRA</b> s	National Regulatory Authorities
<b>CIP</b>	Coalition of Interested Partners	<b>PHE</b> s	Public Health Emergencies
<b>CPP</b>	Certification of Pharmaceutical Products	<b>PIC/S</b>	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
<b>CRP</b>	Collaborative Registration Procedure	<b>PIDM</b>	Programme for International Drug Monitoring
<b>EAC</b>	East African Community	<b>PPCs</b>	Preferred Product Characteristics
<b>ECOWAS</b>	Economic Community of West African States	<b>PQ</b>	Prequalification
<b>EDL</b>	Essential Diagnostics List	<b>PSPQ</b>	Programmatic Suitability for Prequalification
<b>EML</b>	Essential Medicines List	<b>SADC</b>	Southern African Development Community
<b>ERP</b>	Expert Review Panel	<b>SBPs</b>	Similar Biotherapeutic Products
<b>EUAL</b>	Emergency Use Assessment and Listing (replaced by EUL)	<b>SEARN</b>	South East Asia Regulatory Network
<b>EUL</b>	Emergency Use Listing	<b>SF</b>	Substandard and Falsified
<b>FPP</b>	Finished Pharmaceutical Product	<b>SMART</b>	Specific, Measurable, Achievable, Relevant, Time-Bound
<b>GBT</b>	Global Benchmarking Tool	<b>TPPs</b>	Target Product Profiles
<b>GMP</b>	Good Manufacturing Practice	<b>UHC</b>	Universal Health Coverage
<b>GPW13</b>	WHO 13th General Programme of Work	<b>UNICEF</b>	United Nations Children's Fund
<b>GSMS</b>	Global Surveillance and Monitoring System	<b>VCP</b> s	Vector Control Products
<b>GVSI</b>	Global Vaccine Safety Initiative	<b>WHOPES</b>	WHO Pesticide Evaluation Scheme
<b>HIC</b> s	High-income Countries	<b>WLA</b> s	WHO Listed Authorities
<b>ICDRA</b>	International Conference of Drug Regulatory Authorities		
<b>ICH</b>	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use		
<b>ICMRA</b>	International Coalition of Medicines Regulatory Authorities		





# Executive Summary

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WHO's 2019–2023 Plan to help build effective and efficient regulatory systems is designed to assist national regulators to deliver regulation that protects the public while enabling timely access to quality products and encouraging innovation. Closely aligned with WHO's 13<sup>th</sup> General Programme of Work (GPW13), this Plan prioritizes regulatory initiatives to help our Member States increase access to universal health coverage (UHC), support health emergency responses, and promote healthier populations. Building on its current activities, annual work plans with specific deliverables and key performance indicators (KPIs) will be

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