DELIVERING QUALITY-ASSURED MEDICAL PRODUCTS FOR ALL

2019–2023

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

World Health Organization

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Foreword

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 Pharmaceuticals
Geneva, 2019

Abbreviations

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

Executive Summary

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 13th 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