World Health Organization

WHO Activities on Regulation of Medicines and other Health Technologies

Problème de qualité des médicaments dans les pays émergents à faible et moyen revenu

17 October 2018
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Key Themes of WHO's 13th General Programme of Work 2019-2023

Mission

Promote Health - Keep the World Safe - Serve the Vulnerable

Strategic Priorities

Health Coverage: 1 billion more people with health coverage
Health Emergencies: 1 billion more people made safer
Health Priorities: 1 billion lives improved

WHO Regulatory Activities to Strengthen Regulatory Capacity and Quality of Medical Products

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Technologies, Standards and Norms

- Global norms and standards
- Common understanding on regulatory requirements by authority and manufacturer
- Standardized approach used by quality control laboratories
- Decreased work for authorities and manufacturers

Regulatory Systems Strengthening

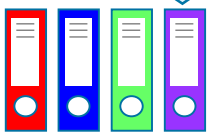
- Collaborative & harmonized regulatory approaches in LMICs
- Faster/smoother registration
- Increased confidence in product quality, safety and efficacy
- Decreased cost & time of regulatory activities
- Local Production

Prequalification Programme

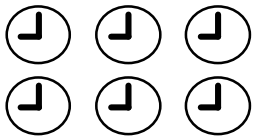
- Qualify assured medicines, vaccines, medical devices, cold chain equipment, vector control products and more accurate diagnostics for use in LMICs
- Increased competition to shape the market
- patients to access quality medical products

Safety & Vigilance

- Increased knowledge of real life adverse events
- Coordinated actions taken against adverse events
- Protection against substandard / falsified products
- Containing antimicrobial resistance



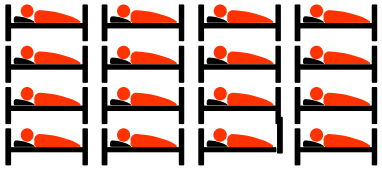
Decreased regulatory burden



Reduced time for regulation

Increased regulatory capacity in LMIC

Decreased cost of regulation



Reduced mortality and morbidity

Some of WHO's regulatory activities:

- Global Benchmarking Tool (GBT) to assess National Regulatory Authority (NRA) capacity and identify gaps, followed by assisting NRAs to develop Institutional Development Plan (IDP)
  - One indicator specifically focused on evaluating capacity to prevent, detect and respond to substandard or falsified medicines
- Promoting reliance and facilitated market authorization pathways, including joint assessment and collaborative Registration Procedures (CRP)
- Supporting convergence and harmonization and regulatory networks
  - AVAREF (African Vaccine Regulatory Forum)
  - AMRH (African Medicines Regulatory Harmonization) initiative
  - CRS (Caribbean Regulatory System)
  - SEARN (South East Asia Regulatory Network)
- Setting technical guidance – e.g. guidance on testing of suspect falsified medicines
- Surveys to evaluate quality throughout the distribution chain
- Global Surveillance and Monitoring System

Regulatory Systems Strengthening (RSS)

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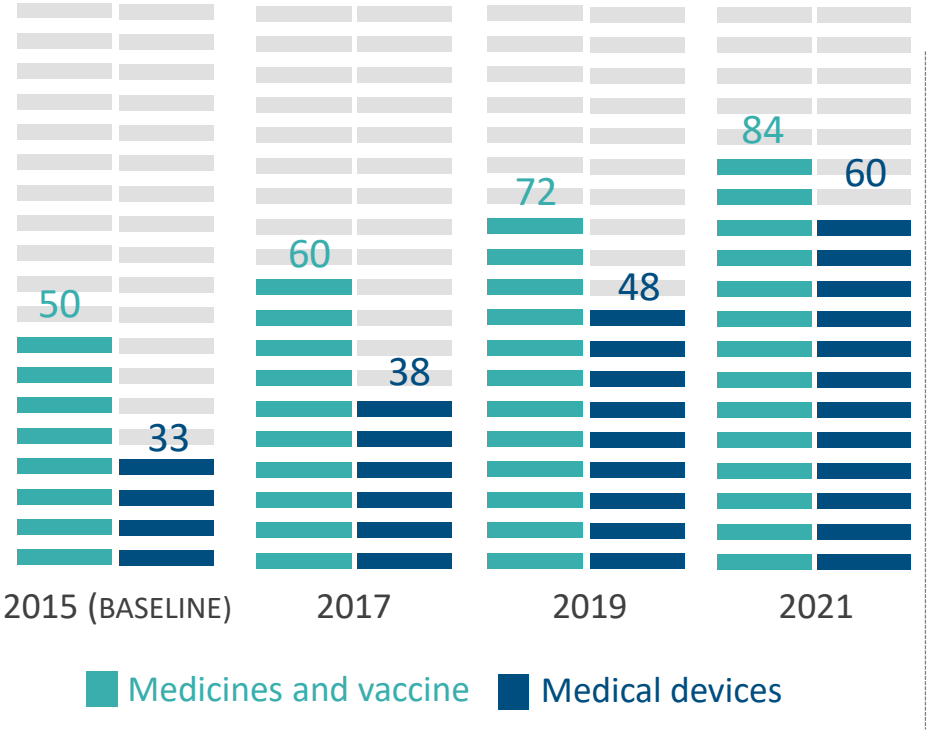
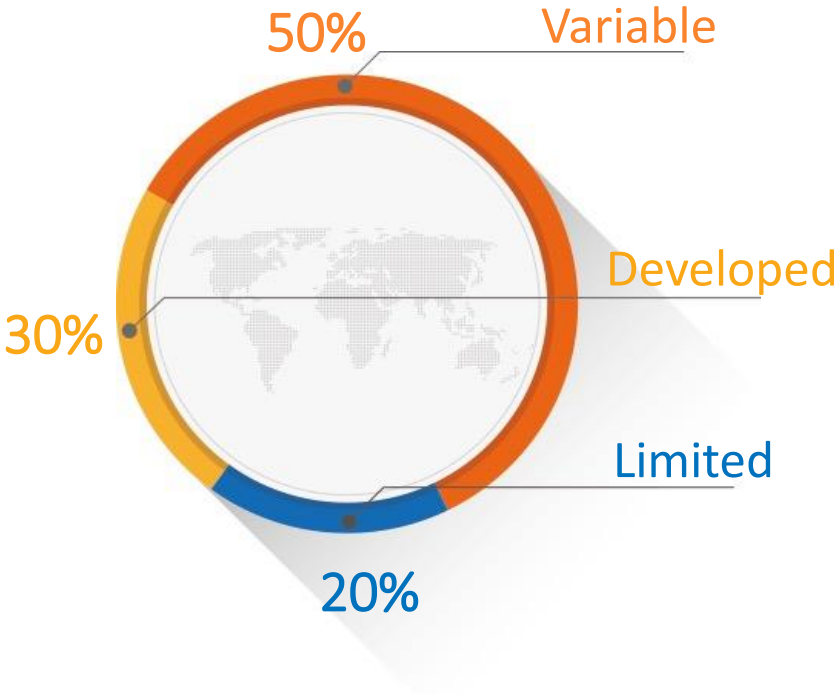
Some of the global challenges that need to be addressed

Functionality of National Regulatory Authority



194 WHO Member States



≈30% of NRAs globally have capacity to perform all core regulatory functions for medicines (much less for biotherapeutic products and medical devices)

WHO GBT Performance Maturity Levels

(for medicines and vaccines)

World H
Organiz

ISO 9004

WHO GBT

1

NO FORMAL APPROACH

Some elements of regulatory system exist

2

REACTIVE APPROACH

Evolving national regulatory system that partially performs essential regulatory functions

3

STABLE FORMAL SYSTEM APPROACH

Stable, well-functioning and integrated regulatory system

4

CONTINUAL IMPROVEMENT EMPHASIZED

Regulatory system operating at advanced level of performance and continuous improvement

Can be consider as functional if rely on other regulators for some specific functions

Target of WHA Resolution 67.2

Advanced/reference Regulatory Authorities

99
COUNTRIES

45
COUNTRIES

50
COUNTRIES

Système Mondial de Surveillance et de Suivi

Disponible en **Anglais, Français et Espagnol**

150
états membres formés

700
personnel règlementaire formés

18
agences d'approvisionnement sensibilisées

2000
produits suspects notifiés

110
pays où des incidents ont eu lieu

24
Alertes Médicales de l'OMS et nombreuses alertes régionales

24
ateliers de formations dans toutes les régions

Assistance technique de l'OMS dans plus de **100** cas

Publications OMS sur les produits médicaux de qualité inferieure et falsifiés (Novembre 2017)

Preuves validées pour comprendre la situation mondiale et identifier les vulnérabilités et d'influencer les changements

Étude de l'impact socioéconomique et sur la santé publique

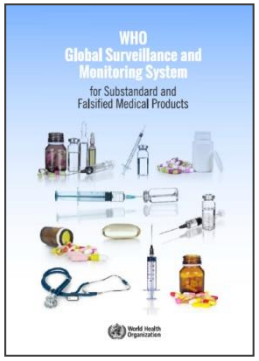
www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en

Demande spécifique du Dispositif des États Membres, avec pour objectifs:

✓ **FONDÉE SUR DES PREUVES**
Fournir des informations et quantifier le coût et l'impact socioéconomique des médicaments de qualité inferieure et falsifiés

✓ **ÉVALUER L'ÉTENDUE DU PROBLÈME**
Méthode suggérée dans la section limitations / discussions

✓ **PLAIDOYER POUR DAVANTAGE D'ATTENTION ET D'INVESTISSEMENT**
Établir les coûts et les avantages potentiels du renforcement des systèmes de réglementation pour sécuriser la chaîne d'approvisionnement des produits de santé



Rapport du Système Mondial de Surveillance et de suivi

www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/

Publié conjointement avec l'étude d'Impact

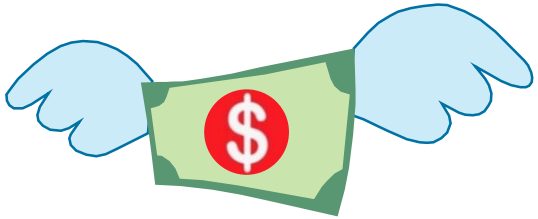
- ✓ Rapport des 4 premières années d'activités du Système Mondial de Surveillance et de suivi: preuves vs anecdote
- ✓ Analyses quantitatives et qualitatives de la base de données reposant sur les notifications
- ✓ Nombreuses études de cas et exemples de terrain
- ✓ Identifie les faiblesses techniques et structurelles, et propose un cadre pour une stratégie globale PRÉVENTION-DÉTECTION-INTERVENTION
- ✓ Défaillances des systèmes de santé et faiblesses des chaines d'approvisionnement

Résultats clefs de l'étude d'impact

10.5%

Taux d'échec observé agrégé des échantillons analysés dans les pays à revenu faible ou intermédiaire

US$ 30.5 BILLION

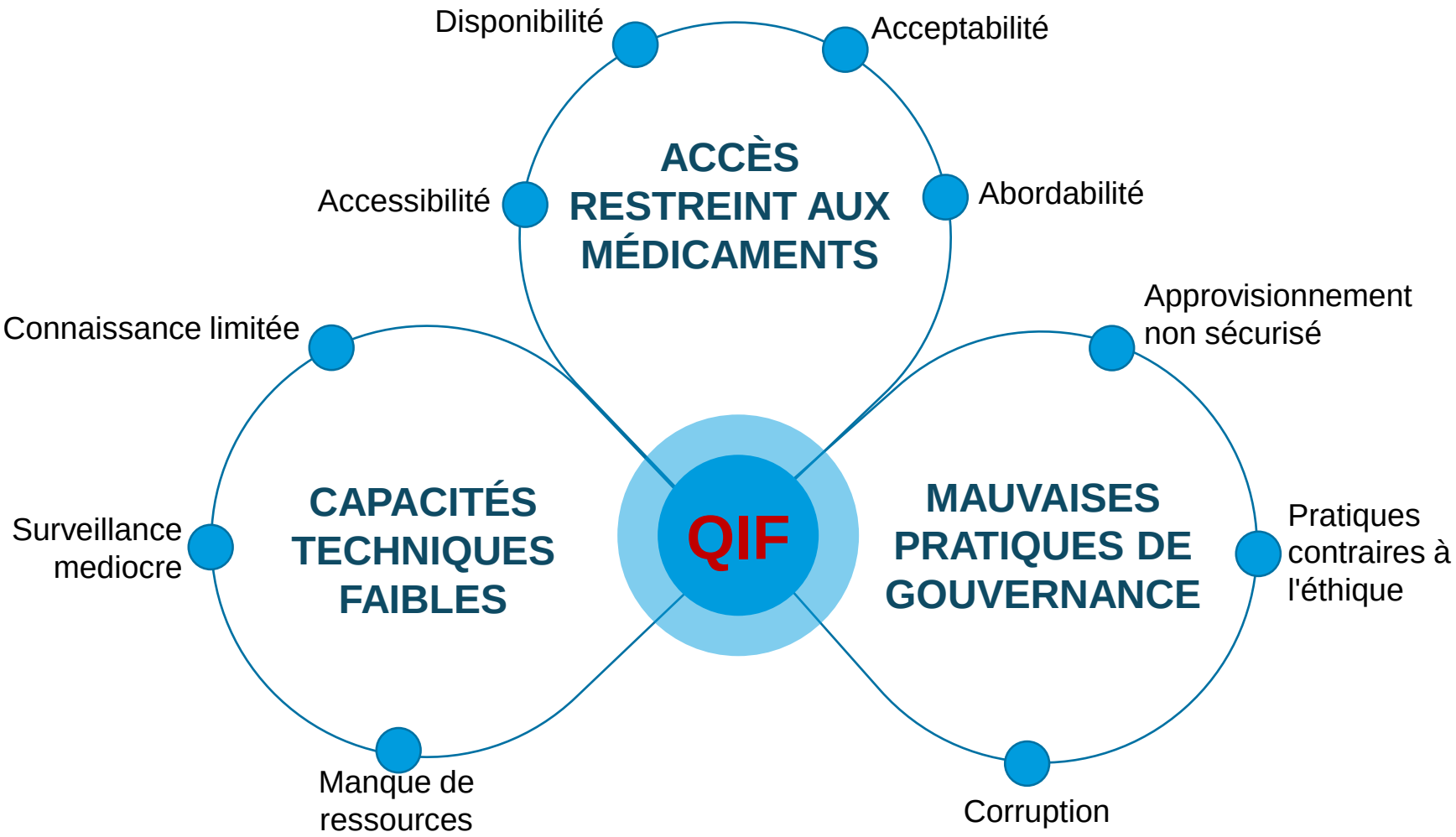


dépenses estimées sur les produits de qualité inferieure et falsifiés dans les pays à revenus faibles ou intermédiaires basées sur les ventes pharmaceutiques non pondérées

http://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/

Forces motrices

La qualité est la plus menacée lorsque toutes ces forces convergent



QIF: produits médicaux de qualité inferieure et falsifiés

Messages clefs

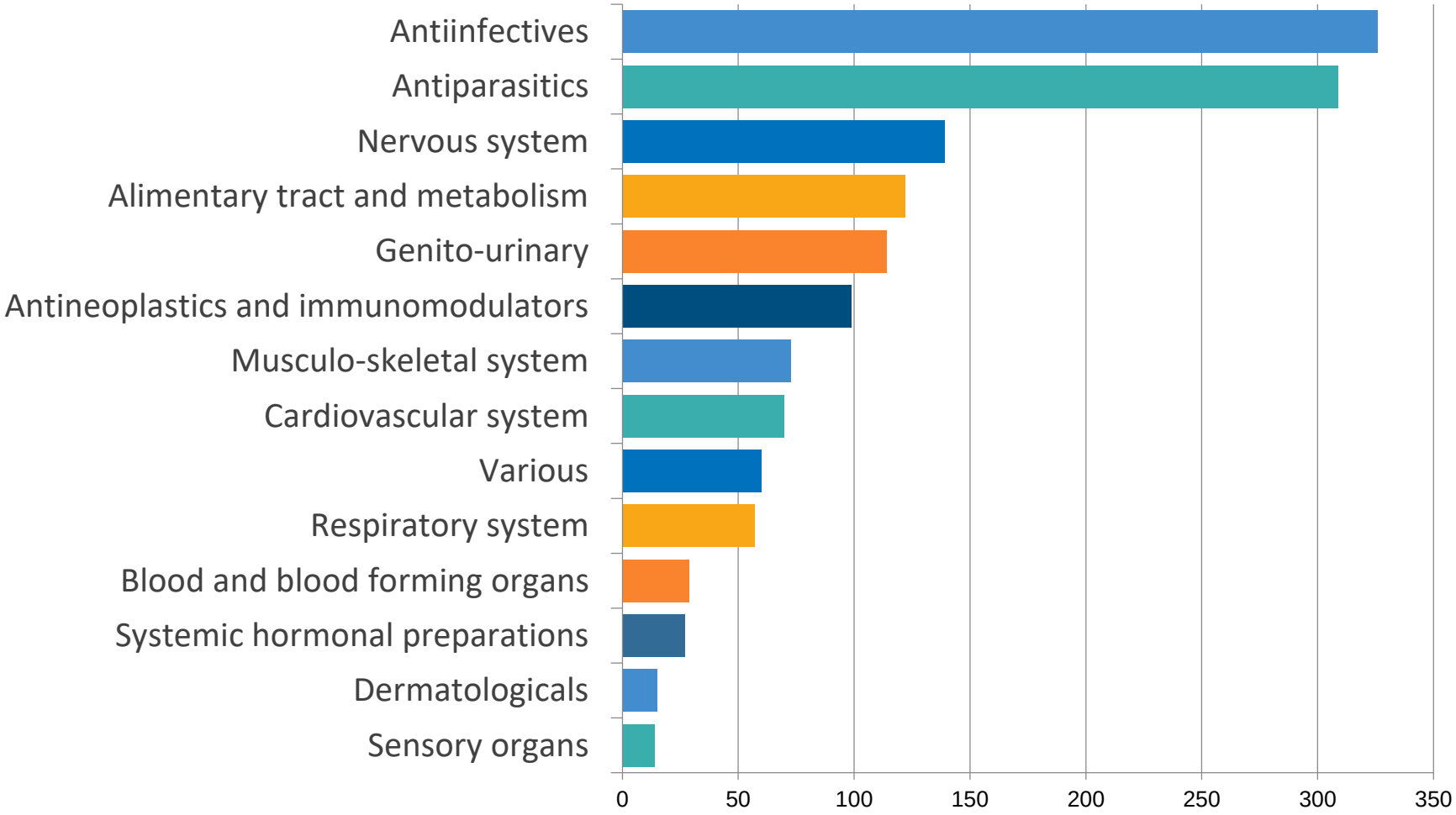
DE LA POLITIQUE GLOBALE À L'IMPACT LOCAL	la **VOLONTÉ POLITIQUE** est nécessaire pour traduire la politique convenue au niveau mondial en **ACTIONS DURABLES** sur le terrain, dotées des **RESSOURCES FINANCIÈRES ET HUMAINES APPROPRIÉES**
STRATÉGIES D'INVESTISSMENT FIABLES	le **RENFORCEMENT DE LA CAPACITÉ ET DES SYSTÈMES DE RÉGLEMENTATION** est une étape clé et un **INVESTISSEMENT JUDICIEUX** pour protéger la fabrication, la distribution et la fourniture de produits médicaux
COOPERATION ET COORDINATION	Des **SYSTÈMES DE NOTIFICATION** améliorés et une plus grande **TRANSPARENCE** au sein des pays et entre eux sont nécessaires, ainsi qu'un **ENGAGEMENT LARGE ET EFFICACE ENTRE PLUSIEURS PARTIES PRENANTES**

Access to quality medicines and other health technologies

requires
an integrated approach
across all regulatory activities

Produits médicaux notifiés à la base de données, par catégorie thérapeutique

WHO GSMS data: 2013-2017



http://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en

WHO survey on antibiotic & anti-malaria medicines:

in selected African countries

Objectives of the study:

- To examine product information meets WHO norms and standards and is the same as the information provided during the prequalification of the product
- To evaluate quality of products from three levels of the distribution chain
- To improve understanding of impact of substandard and falsified (SF) medical products on antimicrobial resistance
- To verify suitability of laboratory tools for detection of SF products
- To assess product quality compliance with authorized specifications and standards
- To determine the proportion of SF products

Current status:

- Countries are being selected: focus on West Africa and regional approach to be used
- Products to be sampled have been selected
- Collaboration with USFDA, USP and others

WHO Guidance on testing of "suspect" falsified medicines (Technical Report Series 1010, Annex 5, 2018)

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- Provide technical guidance on laboratory testing of suspected samples detected and related aspects of sampling and reporting
- To be read in conjunction with the guidelines on sampling and market surveillance

Roles of WHO:

- Setting technical standards on quality assurance of pharmaceutical products and other topics that are relevant to the regulatory oversight of medical products, including
  - guidance on registration,
  - good manufacturing practices (GMP),
  - good distribution practices (GDP),
  - quality control (QC) testing of medicines

Roles of National Regulatory Authorities:

- Establish rules (national legislation and regulations) and instruments that control the production, distribution and commercialization of medical products
- Provide rigorous regulatory oversight, including
  - Postmarketing surveillance,
  - Protecting the supply chain against infiltration of such products

https://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/