Perspectives of international organisations: World Health Organisation

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Quality assurance for radiopharmaceuticals: The International Pharmacopoeia

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The world has made tremendous progress in improving global health compared to seventy-five years ago.
Persistent global inequalities in access to health products and healthcare limits our collective ability of achieving good health and well-being for all.

The UHC service coverage index (SDG indicator 3.8.1) increased from 45 in 2000 to 67 in 2019.¹ Almost 2 billion people are facing catastrophic or impoverishing health spending (SDG indicator 3.8.2).¹

Many health products in low-and middle-income settings are often of poor quality, unaffordable, poorly regulated, or unsafe, leading to preventable morbidity and mortality.

Half of cancer patients in low and middle-income countries do not have access to radiotherapy²

“Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all” (SDG 3 target)
Persistent global inequalities in access to health products and healthcare disproportionately affect low-income settings.

Performance on the UHC effective coverage index and 23 effective coverage indicators, by location, in 2019.³
“The knowledge and the tools required for the improvement of health in ALL countries are available. YET only a very small proportion of men, women and children of the world at present enjoy the benefits to health that science can bring”

Foreword in the Report to the First World Health Assembly in 1948 by A.STAMPAR, M.D, Chairman of the Interim Commission
WHO uses a differentiated approach to drive impact in every country and to achieve its mission

WHO’s mission

Promote health – keep the world safe – serve the vulnerable

Strategic shifts

Stepping up leadership – diplomacy and advocacy; gender equality, health equity and human rights; multisectoral action; finance

Drive public health impact in every country – differentiated approach based on capacity and vulnerability

Policy dialogue – to develop systems of the future
Strategic support – to build high performing systems
Technical assistance – to build national institutions
Service delivery – to fill critical gaps in emergencies

Mature health system
Fragile health system

Focus global public goods on impact – normative guidance and agreements; data, research and innovation
Robust regulatory systems facilitates equitable access to quality assured, safe and effective health products contributing to healthy lives and well-being for all everywhere.

- Strengthening regulatory systems for medical products
- Improving the availability of affordable quality, safe, and effective products worldwide
- Achieving global health priorities such as the United Nations Sustainable Development Goals (SDG)
- Ensuring healthy lives and promote well-being for all at all ages
### Technologies, Standards and Norms
- Set global norms and standards (written & physical) and nomenclatures
- Increase common understanding on regulatory requirements by authority and manufacturer
- Standardize approach used by quality control labs

### Regulatory Systems Strengthening
- Set effective and efficient regulatory systems in LMICs through collaborative & harmonized approaches with reliance principles
- Increase confidence in medical products produced in LMICs

### Prequalification Programme
- Assure safety, quality, efficacy & appropriateness of medical products used in LMICs: vaccines, medical devices, cold chain equipment, vector control products & in vitro diagnostics
- Increase competition to shape the market

### Safety & Vigilance
- Increase knowledge of real life adverse events and coordinate actions taken against adverse events
- Mitigate risks and protect against substandard / falsified products
- Contain antimicrobial resistance

### Outcomes
- Decreased regulatory burden
- Reduced time for regulation
- Increased regulatory capacity in LMIC
- Decreased cost of regulation
- Reduced mortality and morbidity

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Adapted from Emer Cooke, 2019
(Article 2 (u) ..to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products;

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<th>Key problems</th>
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<td>Different pharmacopoeia standards</td>
<td>Publish and maintain global quality standards</td>
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<td>Quality and safety concerns</td>
<td>Increased access to quality and safe medicines</td>
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<td>&lt; 60 countries covered by national or regional pharmacopoeia</td>
<td>Facilitates international trade</td>
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Supports equitable access to quality assured medicines as part of universal health coverage and health for all
Results framework for norms and standards for health products linking the problems to the intended public health impact

1. Lack of or poorly defined norms and standards for health products, especially in LMICs contribute to (a) substandard or falsified products; (b) unsafe or ineffective products used in those settings, leading to preventable morbidity and mortality.

2. Most LMICs lack access to affordable quality health products.

Inputs
- Available expertise and technical knowledge on health products and regulatory frameworks.
- Funding and resources for developing, implementing, and monitoring norms and standards for health products.
- Collaboration and partnerships with Member States, industry, civil society, and other stakeholders.
- Tools for efficient and effectively engaging, collaborating, and disseminating the standards for health products.

Activities
- Develop and update WHO (i) written standards, (ii) physical standards and technical specifications, and (iii) other relevant documents (implementation support materials, learning materials) through the Expert Committees.
- Disseminate and make the standards easily accessible to users.
- Advocate and communicate to increase awareness of WHO norms and standards for health products to key stakeholders.
- Provide technical assistance and capacity building to Member States to implement WHO recommendations for health products.

Outputs
- (a) Updated WHO norms and standards
- (b) Availability and accessibility of WHO norms and standards for health products
- (c) Advocacy and communication materials; (d) information sessions
- (e) Trained competent personnel; (f) countries supported

Outcomes
- Introduction of, and increase in the number of quality products following WHO recommendations
- Defined national standards that meet WHO recommendations

Impact
- Improved equitable access to safe, effective, quality and affordable health products for all populations, particularly those in low- and middle-income countries.
Pharmacopoeias establish quality standards for pharmaceutical products, including radiopharmaceuticals ensuring their safe and effective use.

Pharmacopoeias help to prevent substandard or falsified medicines from entering the market by setting acceptable and appropriate quality standards for pharmaceutical products.

Regulatory agencies use pharmacopoeias to evaluate and approve new medicines and monitor the quality of medicines already on the market.

Provide information on the proper storage and handling of medicines, which helps to ensure their effectiveness.

(1) not all countries or regions maintain or publish pharmacopoeias

(2) medicines that are a priority in other settings, such as neglected or tropical diseases, are not covered

(3) there is need to harmonize or unify the quality standards to streamline regulatory requirements
The International Pharmacopoeia, published by WHO, provides a valuable resource, especially to countries that do not have public standards to control the quality of products in their market.

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More than 40 countries officially refer to the International Pharmacopoeia

WHO prequalification is used by UN agencies and all major global procurement agencies supplying to LMICs
WHO and IAEA have been collaborating to develop public standards for radiopharmaceuticals.


- Maintaining International Pharmacopeia relies on **collaboration and expertise from all stakeholders** to ensure that information published is based on **available scientific evidence** focusing on key priority public health needs, especially to ensure equity in access to healthcare and related services, including radiopharmaceuticals.
WHO also maintains a compendium of guidelines to facilitate the development, production, distribution, storage and use of pharmaceuticals.

*Covers today* WHO’s Norms and Standards for Pharmaceuticals:

- Quality control
- Regulatory standards
- Inspection
WHO and IAEA collaborate to publish specific quality assurance guidelines for radiopharmaceuticals


The recommendations in this guideline are applicable to:

- the production, preparation or compounding of radiopharmaceuticals in hospital radiopharmacies, including diagnostic and therapeutic products;
- the production or compounding of radiopharmaceuticals in centralized radiopharmacies;
- the production or compounding of radiopharmaceuticals in nuclear centres and institutes;
- the production of radiopharmaceuticals by industrial manufacturers; and
- the production of cyclotron-based radiopharmaceuticals.
WHO and IAEA collaborate to publish specific quality assurance guidelines for radiopharmaceuticals

IAEA/WHO guideline on good manufacturing practices for investigational radiopharmaceutical products

This guidance provides recommendations on the acceptable and appropriate standards that should be in place when preparing novel radiopharmaceuticals for phases I–III clinical investigations that do not have a marketing authorization.


provides specific requirements for manufacturing investigational radiopharmaceuticals used in early and late clinical trials.


describe the general principles for investigational products used in early and late clinical trials.
Health For All envisions that all people have good health for a fulfilling life in a peaceful, prosperous, and sustainable world.
References


Thank you

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