



Raffaella Balocco Mattavelli

World Health Organisation



Products Standards, Specifications
and Nomenclature Unit (PSN)

INN Programme

Every Product. Every Patient. Everywhere.

PTMG, Prague 2026

Every Product. Every Patient. Everywhere.

Why names matter more than we think ?



Every Product. Every Patient. Everywhere.

Diverse Medicinal Products

Medicinal products range from simple pain relievers to complex biologics, reflecting global healthcare diversity.

Human Dimension of Healthcare

People of all ages and cultures rely on medicines daily, often during vulnerable moments.

Global Reach of Medicines

Medicines cross borders via trade, aid, and supply chains, highlighting the interconnected healthcare system.

Importance of Medicine Names

Medicine names provide clarity and trust, connecting patients, professionals, and regulators worldwide.



Imagine a world without INN (research)

- Ibuprofen
- Ibuprofeno
- Brufen
- Nurofen
- Advil

'Quite a noisy meeting...'



Imagine a world without INN (Shipping)

- Ibuprofen
- Ibuprofeno
- Brufen
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- Advil

'Quite a noisy meeting...'



Imagine a world without INN (patients)

- Ibuprofen
- Ibuprofeno
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- Advil

'Quite a noisy meeting...'

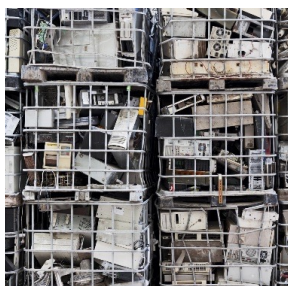


Imagine a world without INN



Communication Breakdown Scenario

Imagining a meeting where everyone speaks different languages highlights confusion and frustration in communication.



Healthcare Without Common Language

Without INN, healthcare professionals struggle to communicate, risking patient safety and global coordination collapse.



Value of Naming Standardization

Standardized naming like INN ensures safety, understanding, and effective global healthcare communication.

One Medicine. One Name. One Language.



Unified Naming Philosophy

The phrase emphasizes the importance of consistency, clarity, and universality in medicine naming.

Patient Safety

A single recognized name ensures accurate prescribing and monitoring, enhancing patient safety.

Global Communication

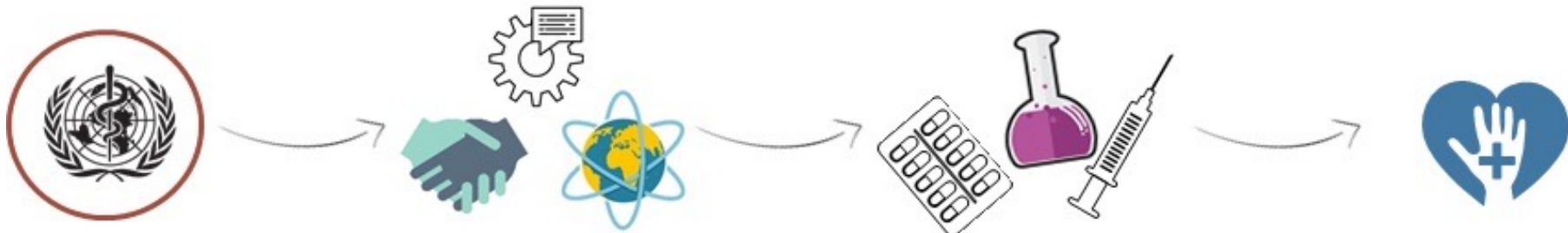
Consistent naming enables clinicians and regulators worldwide to communicate effectively.

Access and Pharmacovigilance

Unified names improve medicine access and support detection of safety signals worldwide.

Norms & Standards: WHO Core Business

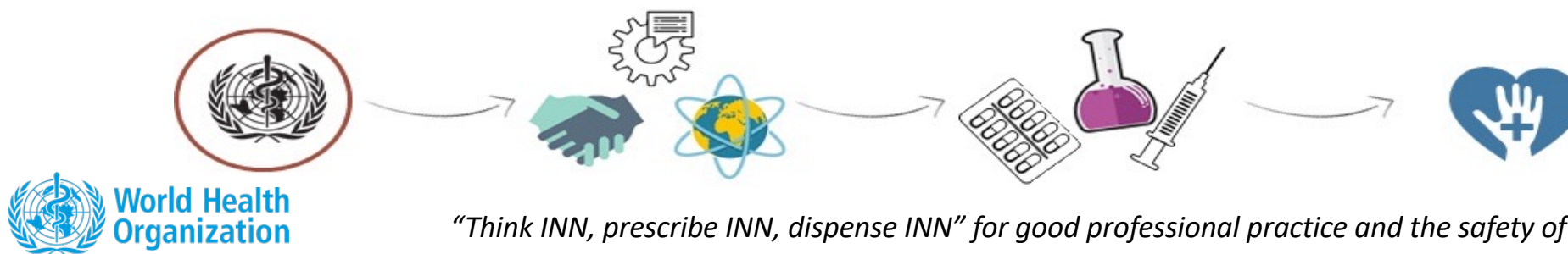
The Constitution requires WHO“ to develop, establish and promote **INTERNATIONAL STANDARDS** with respect to biological and pharmaceutical **products**”.



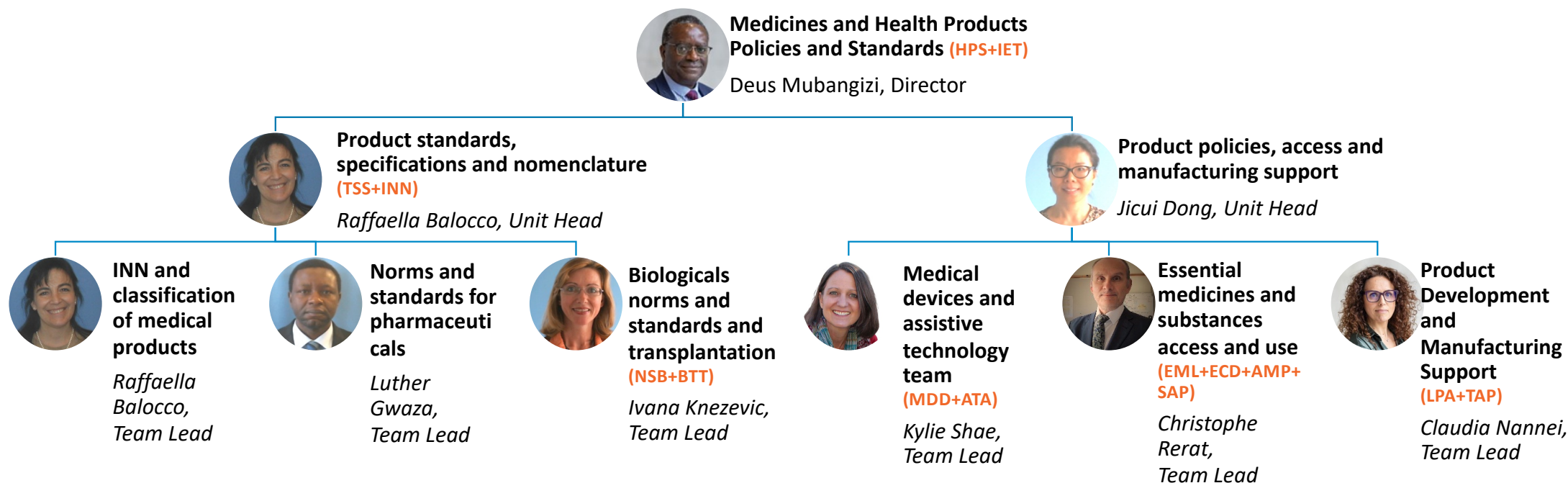
Norms & Standards: WHO Core Business

Assistant Director General, Health Systems, Access and Data (HSD)		
		Sylvie Briand
Director, Regulation and Prequalification (RPQ)		Rogério Gaspar
Director, Medicines and Health Products Policies and Standards (HPS)		Deus Mubangizi
Director, Data, Digital Health, Analytics and AI (DDA)		Alain Labrique
Director, Antimicrobial Resistance (AMR)		Yvan Hutin
Director, Performance, Financing and Delivery (PFD)		Kalypso Chalkidou
Director, Global Traditional Medicine Centre (TMC)		Shyama Kuruvilla (Acting)
Director, WHO Academy (ACD)		Sylvie Briand

Director(s) position
remain vacant at this
stage, with the current
transitional
arrangements



Organizational chart



Department of Medicines and Health Products Policies and Standards Functional Structure

Product Standards, Specifications and Nomenclature Unit

International Nonproprietary Names Team

- International Nonproprietary Names
- ATC and DDD

Biologicals Norms and Standards and Transplantation Team

- Regulatory standards for biologicals
- Standards and guidance for blood systems
- Standards and guidance for transplantation systems

Norms and Standards for Pharmaceuticals Team

- Regulatory standards for pharmaceuticals
- The International Pharmacopoeia

Product Policies, Access and Manufacturing Support Unit

Medical Devices and Assistive Technology Team

- Essential and priority lists (EDL, MDL, APL)
- Procurement, provision, management and safe use
- Harmonization of medical devices nomenclature

Essential Medicines and Substances Access and Use Team

- Model List of Essential Medicines
- Access to and safe use of controlled substances
- Affordability and availability; application and management of IP
- Supply security; procurement and supply chains

Product Development and Manufacturing Support Team

- Geographically diversified manufacturing and tech transfer
 - mRNA, HTAP, Ecosystem assessment, global coordination
- WHO Biomanufacturing Workforce Training Initiative
- PQ/EUL-related specialized technical assistance

WHO and Global Standards



Role in Global Standards

WHO builds global standards that enable systems to function across borders with safety and trust.

Medicine Naming as a Standard

The naming of medicines is a core function establishing shared rules for health governance.

Legitimacy and Neutrality

WHO's standard-setting role reinforces its legitimacy and neutrality in global health management.

Foundations of Global Health

Standard names form the foundation of how global health systems work effectively worldwide.

Established by Expert Committee:



- **INN**: WHO Expert Group on International Nonproprietary Names
- The **International Nonproprietary Names (INN) Programme** was initiated in 1950 by the World Health Assembly to minimize the risk of name confusions and medication errors for pharmaceutical substances and to ensure patient safety.
- The **objective of the INN Programme** is to define a single, unique, globally accepted name for each pharmaceutical substance, including biologicals.
- **INN** support safe prescribing and dispensing, pharmacovigilance, access to medicines, and lower costs of medicinal products.

How an INN Is Created:



Applicant Proposal

Pharmaceutical developers initiate the process by proposing a new drug name to the INN system.

Expert Review

Independent experts conduct a rigorous, neutral scientific review of the proposed name.

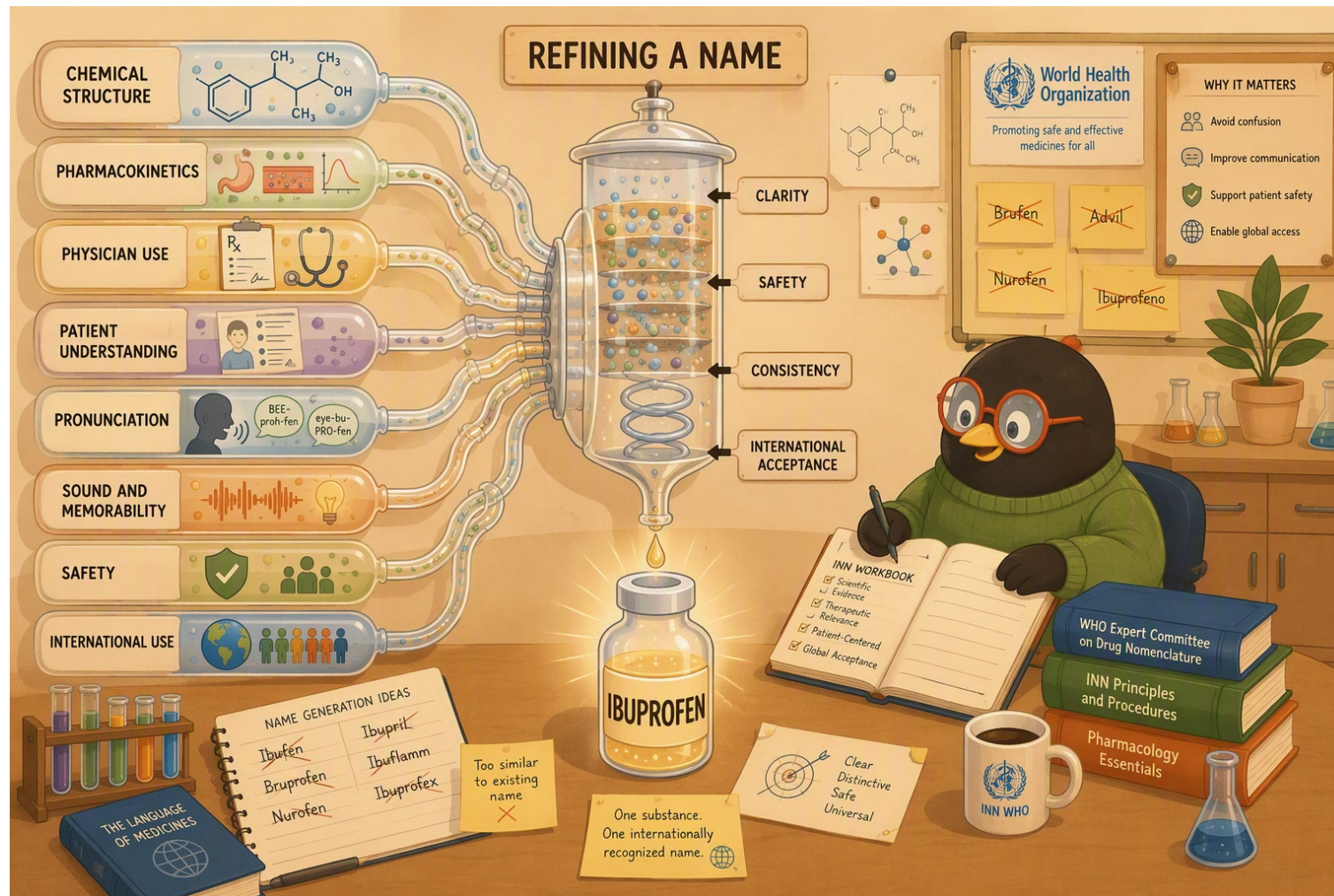
Public Consultation

Stakeholders worldwide provide feedback to identify potential linguistic or confusion issues.

Recommended INN Designation

The name passes review and is designated as a Recommended INN, becoming a global standard.

The Science of Naming



The Science of Naming

Naming is Discovery

Medicine names are discovered to fit characteristics and existing systems, not arbitrarily invented.

Systematic Naming Rules

Names are derived from stems, rules, and conventions that communicate pharmacological relationships.

Naming as Art and Science

Naming combines art and science, guided by purpose rather than branding or arbitrary creativity.

Engaging and Educational

Humor and curiosity help demystify naming, making technical concepts more accessible to audiences.

Procedure For The Selection Of INN

Procedure For The Selection Of Recommended International Nonproprietary Names For Pharmaceutical Substances

Article 1

Proposals for recommended international nonproprietary names and proposals for substitution of such names shall be submitted to WHO on the form provided therefor. The consideration **of such proposals shall be subject to the payment of an administrative fee designed only to cover the corresponding costs of the Secretariat of WHO (“the Secretariat”)**. The amount of this fee shall be determined by the Secretariat and may, from time to time, be adjusted.

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Does Industry Really Pay?



Does Industry Really Pay?

Transparency and Confidence

Addressing payment questions openly shows transparency, building audience trust and engagement effectively.

Value Recognition

Industry fees are seen as recognition of value, supporting a neutral, expert-led global naming process.

Support for Neutral Process

Payments fund a neutral process enabling regulatory approval and global acceptance without influencing control.

Sustainable Funding Model

Sustainable funding through industry fees ensures continued public goods and expert-led initiatives worldwide.

Where the Fee Goes

Stewardship and Responsibility

Fee usage is designed to show careful stewardship, focusing on responsibility over profit for trust and transparency.

Role of Experts

Experts include scientific and linguistic specialists who provide objective evaluation of names to ensure quality.

Digital Platform Infrastructure

The digital platform supports application management, data handling, and global access for efficient operations.

Transparency Through Publications

Publications promote transparency, dissemination, and long-term reference for global community trust.

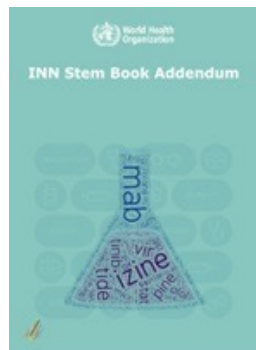
Global Public Good

The program emphasizes serving the international community, highlighting sustainability over profit.

Information that the Applicants need to provide

INN Form	https://extranet.who.int/tools/inn_online_application/INN_online_application_files/INNFORM_072010.pdf
INN Stem	https://www.who.int/teams/health-product-and-policy-standards/inn/stembook
General principles for guidance	https://www.who.int/publications/m/item/who-edm-qsm-2004-5-en
Deadline and more	https://www.who.int/teams/health-product-and-policy-standards/inn/inn-online-application

Stem ad new stem



Guidance on the establishment of new INN stems

<https://www.who.int/teams/health-product-and-policy-standards/inn/stembook>

All about existing stems and pre-stems

<https://www.who.int/teams/health-product-and-policy-standards/inn/stembook>

Stem in a Pill

<https://extranet.who.int/soinn/course/index.php?categoryid=7>

Learning clinical pharmacology with the use of INNs and their stems

<https://www.who.int/publications/m/item/who-emp-rht-tsn-2018-02>

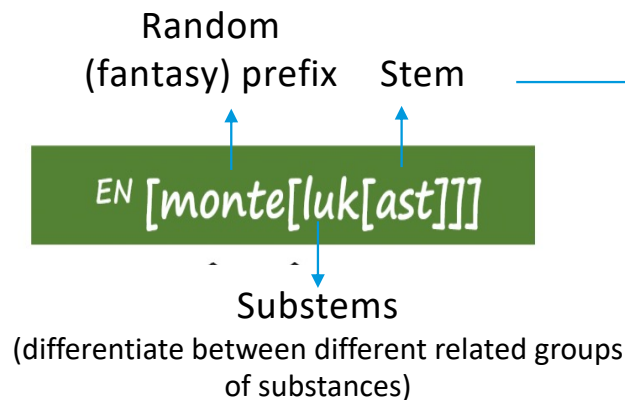
“Think INN, prescribe INN, dispense INN” for good professional practice and the safety of patients

Using INN stems as Benchmarks for Early Signal Detection



- INN structure:

- ast (anti-allergic or anti-inflammatory, not an antihistamine);
- lukast (leukotriene receptor antagonist).



Criteria:

- 1) Mechanism of action,
- 2) Clinical indication,
- 3) Chemical structure.

INN suffixes became indicators of the modes of action or pharmacological classes of the substances.

Therefore, the stem/substem classification system may help identify substances with similar effects on the same target and support the study of shared adverse effects and individual differences.

Challenges in INN nomenclature



Complex Biologics and Biosimilars

Naming biologics requires balancing similarity and distinctiveness to avoid confusion in the expanding pharmaceutical market.

Gene and Cell Therapy Challenges

Novel gene and cell therapies challenge traditional naming systems due to their complexity and innovative nature.

Increasing Name Similarity Risks

The growing number of new medicines raises risks of name similarity and potential confusion among stakeholders.

Role of School of INN

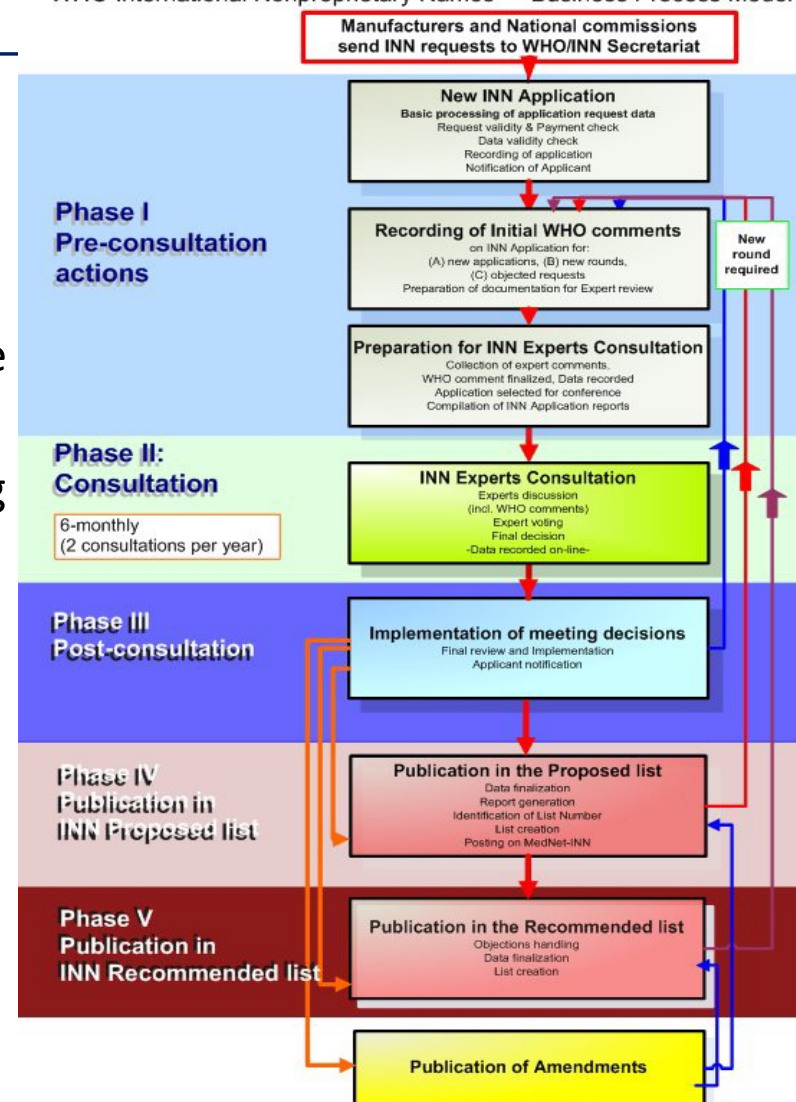
The WHO School of INN provides updated guidance and education to maintain a robust and effective naming system.

INN Flowchart

- The platform provides a unified framework for handling applicant data, process tracking, and downstream publication activities within the ATC and INN domains.
- The system architecture enables interoperable communication through exposed API endpoints to facilitate integration with external and internal services.
- The application environment has been implemented using a stack of open-source technologies to support extensibility, scalability, and maintainability.
- Data processing and workflow orchestration are managed within a centralized digital infrastructure supporting the INN Programme operational processes.
- The overall system environment supports automation of data handling and workflow transitions across the different stages of the INN lifecycle.



WHO International Nonproprietary Names -- Business Process Model



7 Nov. 2005

"Think INN, prescribe INN, dispense INN" for good professional practice and the safety of patients

INN Stakeholders

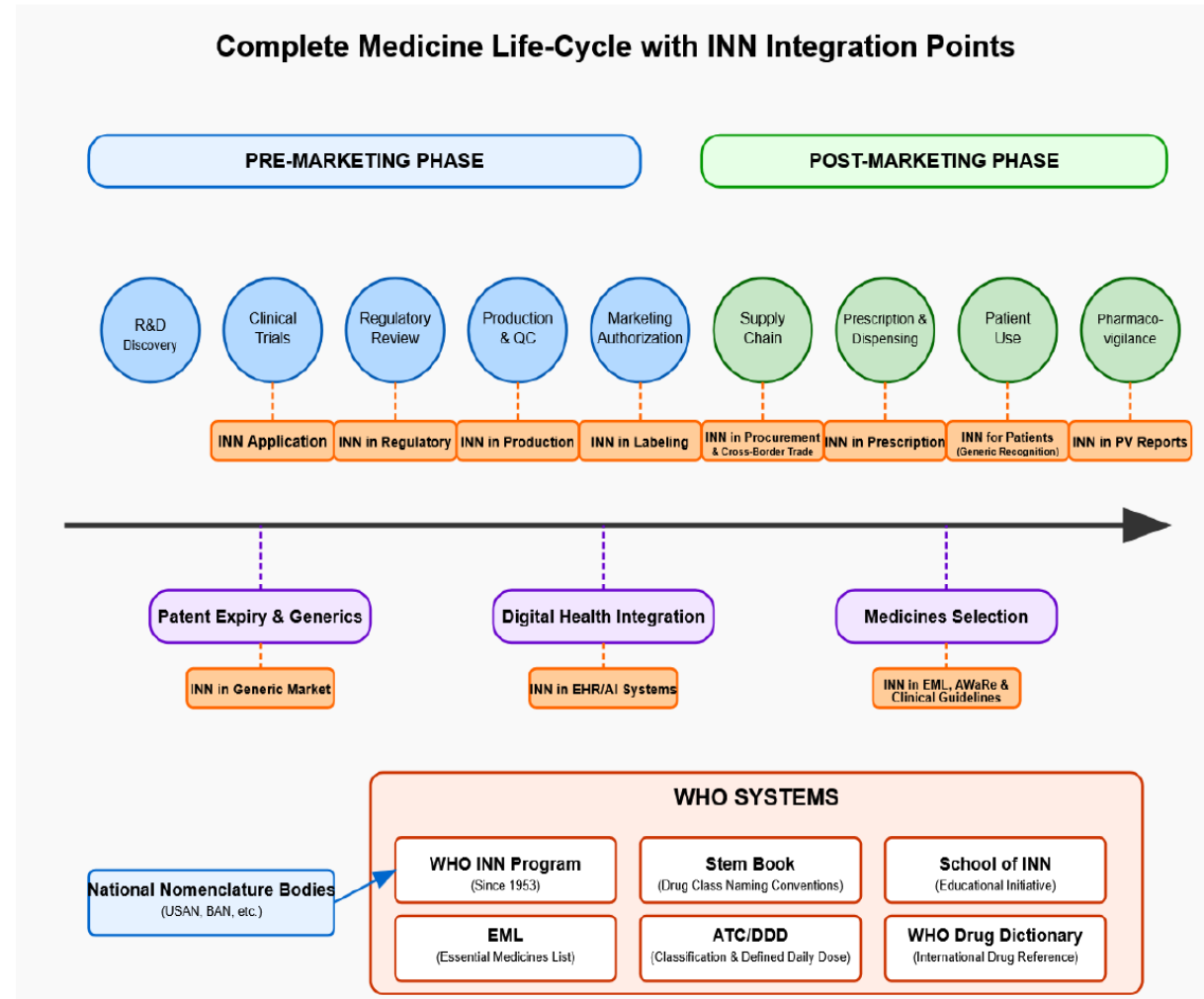


International Nonproprietary Name (INN)

- Unique name
- Distinctive in sound and spelling
- Not liable to confusion with other names in common use
- Formally placed by WHO in the public domain
- Can be used without any restriction to identify pharmaceutical substances

INN Throughout the entire lifecycle of a medicine

Throughout the entire lifecycle of a medicine - from research and development, to regulatory approval, clinical use, and post-marketing - an INN is essential to ensure clarity, global recognition, and patient safety

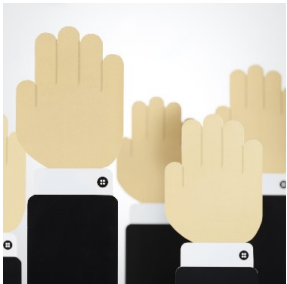


INN as a Global Public Good



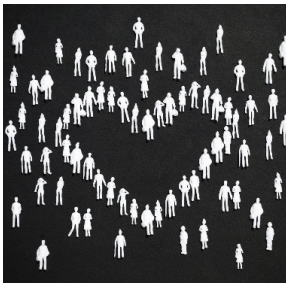
Global Shared System

INN is a universally shared system that benefits everyone without exclusion, emphasizing global cooperation.



Neutrality and Accessibility

INN upholds neutrality and ensures accessibility, promoting collective ownership among diverse stakeholders.



Supports Health Equity

INN aligns with global health values by supporting equity, trust, and solidarity across nations.

Key Messages

World Health Organization
Better names
Better communication
Better health

Names Enable Safety
Clear and precise naming directly enhances patient safety by reducing errors and confusion.

Standards Enable Trust
Consistency and neutrality in standards build trust and facilitate global cooperation effectively.

INN Enables Global Health
International Nonproprietary Names connect naming practices to broader global health outcomes.

One substance
Many names
Global impact

Better names
Better communication
Better health

Working together
for a healthier
world

WHO Expert Committee
on Drug Nomenclature

INTERNATIONAL
STANDARDS

GOOD NAMING PRACTICE

INN
Connecting
Names to
Global Health

Global Health
Clarity
Consistency
Safety
Trust
INN

Key Takeaways

Importance of INN

INN are vital for global health communication, patient safety, and regulatory consistency worldwide.

Role of WHO and School of INN

WHO ensures scientific rigor and neutrality, while the School of INN builds expertise to apply INN effectively.

Growing Complexity of Medicines

As pharmaceutical substances become more complex, understanding and correctly using INN is increasingly important for healthcare outcomes.

Reflective Discussion Benefits

Reflection on INN improves pharmaceutical and clinical practice, as well as regulatory decisions and patient outcomes.

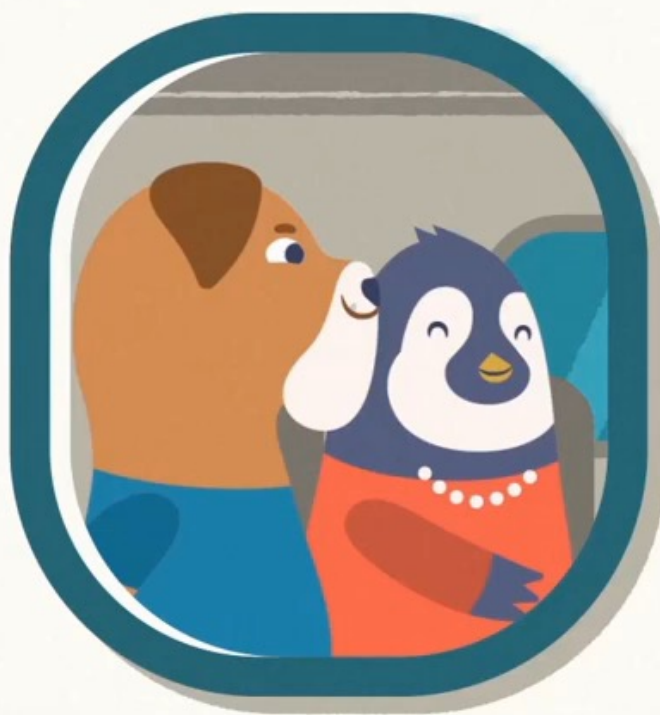
Conclusions



Every medicine
deserves one name.

Every patient deserves
to understand it.

Everywhere we need a
language for all.





Thank you

WHO

20, Avenue Appia
1211 Geneva

Switzerland

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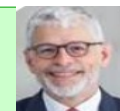
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Powerful Closing



Clarity and Standardization

The message emphasizes the importance of clear and standardized naming for every medicine to ensure consistency.



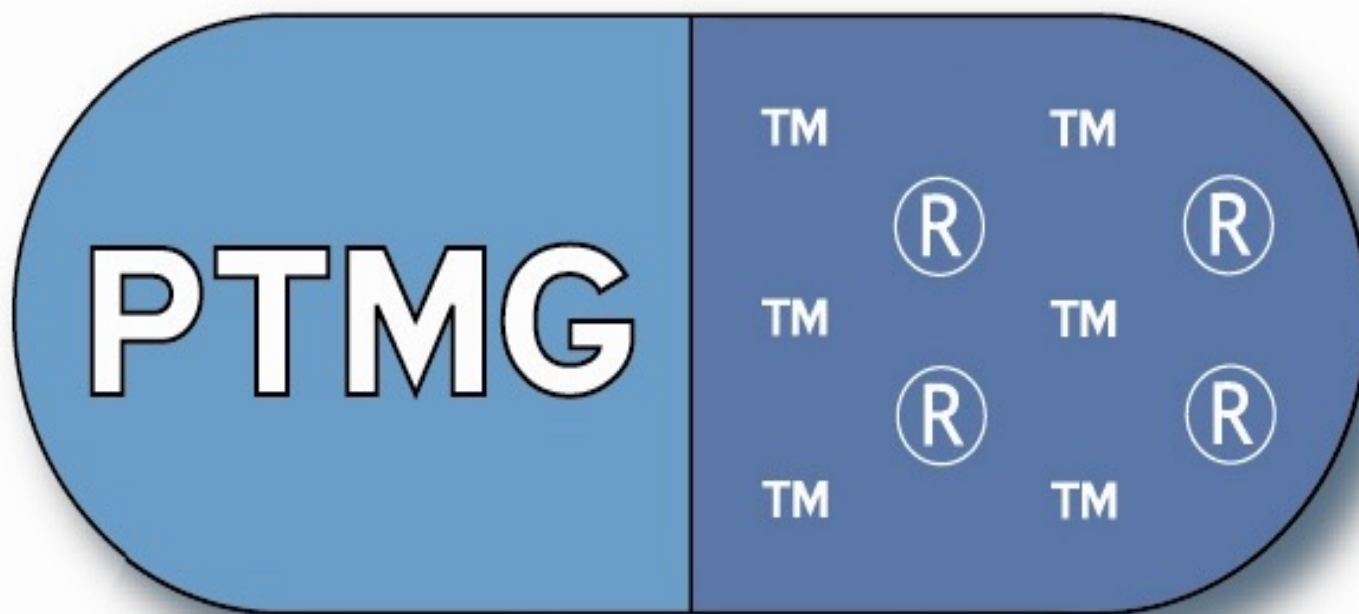
Patient Understanding

Every patient deserves to understand their medicine, highlighting the human-centered approach of the presentation.



Gratitude and Reflection

Ending with thanks invites reflection and reinforces the commitment to patient safety and dignity.



Prague 2026