Questionnaire regarding nomenclatures for concepts related to health technologies

1. Name of the "nomenclature"

   International Nonproprietary Name Programme

2. Name and legal status (Inc, Plc, Ltd, …) of the organization that manages the nomenclature system

   World Heath Organization

3. The organization that manages the nomenclature

   a. Please describe the governance and management of the body responsible for maintaining the nomenclature.

      WHO

   b. How is broad stakeholder representation ensured?

      Very broad stakeholders participation

   c. How is broad geographical representation ensured in governing bodies?

      Very broad geographical representation (all WHO regions); WHO Expert Panel rules applied.

4. Background to the creation of the nomenclature

   Please outline the scope of the mandate to engage in classification and naming

      Article 2 U of WHO Constitution
      WHO WHA Resolution 3.11
      WHO WHA Resolution 43.19

5. What is the intended purpose/use of the system?

   To assign a global name to new medicinal substances, including biologicals
6. **Mandatory use of the nomenclature**
   a. Has any country or organization made it mandatory to use the nomenclature for specific purposes?
   
   Yes. EU, Australia etc.

7. **Please comprehensively describe the structure of the system.**
   The structure and format of terms, the relations between terms, design principles for creating terms etc. Current IT implementations by the "management organization" and by users are also of interest.

8. **Are the terms used in the classification system generic i.e. non proprietary?**
   
   WHO places INNs in the public domain, hence the definition nonproprietary.

9. **Maintenance of the nomenclature system**
   a. **How is the system maintained?**
   
   The INN Expert Group assign new INNs

   b. **Please describe the process for creating or modifying terms in the system.**
   
   See the attached presentation

   c. **How is transparency ensured with regard to development and maintenance of the nomenclature?**
   
   INNs are selected as Proposed INN and published only if the applicant agree; the INN Experts validate the published information (i.e structure etc.). With a circular letter (and also on Web) WHO notify to MS the selected INN. An objection time is offered, should no objection be raised during the permitted time, the INN Reaches the status of Recommended INN and becomes a WHO standard.
   See the attached presentation
10. Different language versions of the nomenclature
   a. How is the translation of terms and definitions managed?
      Six UN official languages. Maintained by WHO INN Programme Secretariat +
      Experts + Collaborating Centre or national Authorities.
      National languages are national responsibilities.

   b. What language versions exist as of February 2011?
      Six UN Languages + many others

   c. What language versions are under translation as of February 2011 ?

11. Endorsement of the nomenclature system
   a. Has the system been endorsed by stakeholders (healthcare professionals, Ministries of
      Health, industry, regulatory bodies etc.)?
      ☑ Yes ☐ No

      Please indicate the names of the entities which have endorsed the system.
      All MS use INN and all stakeholders as well.

12. Implementation in IT systems, interoperability and intellectual property
   a. Please outline the intellectual property state of the nomenclature system. Please
      include reference to the ownership of the terms used.

      Basis WHO WHA Resolution 43,19 ; close collaboration with WIPO and national
      Trade Mark Offices etc.
b. **Is the system available as a package for integration into user IT systems (maintenance management, adverse event reporting, procurement....)?**

   - Yes if no commercial purposes are involved as WHO places INN in the public domain
   - No

b. **Please specify the conditions of agreements for use in user IT systems.**

   - Not allowed for any commercial purpose

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13. **Interoperability**

   **Please specify compatibilities ensured and mappings to other nomenclatures maintained.**

   - INN Global Data hub project

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14. **Model for sustainable financing**

   a. **How is the system financed?** I.e. user fees, member fees, subscriptions, one off payments, open source?

   - Applicants fees

   b. **What is the cost of the nomenclature to specific users (governments, industry, health care providers)?**

   - No cost for national authorities.