Questionnaire regarding nomenclatures for concepts related to health technologies

1. Name of the "nomenclature"

   The Anatomical Therapeutic Chemical (ATC) classification system. The ATC code is linked to the Defined Daily Dose (DDD).

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

   The WHO Collaborating Centre for Drug Statistics Methodology, Oslo, Norway. The Centre is located at the Norwegian Institute of Public Health, Department of Pharmacoepidemiology. Director of the Centre: Hanne Strøm

3. The organization that manages the nomenclature
   a. Please describe the governance and management of the body responsible for maintaining the nomenclature.

   The WHO Centre receives expert advice from the International Working Group for Drug Statistics Methodology (hereafter named Working Group). Members are selected by WHO Headquarters. All decisions concerning ATC codes, DDDs and alterations are approved by the Working Group.

   b. How is broad stakeholder representation ensured?

   NA. The WHO Collaborating Centre for Drug Statistics Methodology (hereafter named WHO Centre) is fully funded by the Norwegian government.

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

   The International Working Group comprises 12 members drawn from the WHO Expert Advisory Panels for Drug Evaluation and for Policies and Management. The members represent different users of the ATC/DDD system and different nationalities as they represent the 6 WHO global regions.

4. Background to the creation of the nomenclature

   Please outline the scope of the mandate to engage in classification and naming
The latest re designation of the Department of Pharmacoepidemiology, Norwegian Institute of Public Health, as a WHO Collaborating Centre for Drug Statistics Methodology, was in May 2008. According to the Agreement, these are the terms of reference for the WHO Centre:

- To classify drugs according to the ATC system
- To establish defined daily doses (DDDs)
- To review and revise as necessary the ATC classification system and DDDs
- To stimulate and influence the practical use of the ATC system
- To organize training courses in the ATC/DDD methodology
- To provide technical support to countries in setting up their national medicines classification systems and build capacity in the use of medicines consumption information

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

The ATC classification system and the DDD as a measuring unit are recommended by the WHO for drug utilization studies. The purpose of the ATC/DDD system is to serve as a tool for drug utilization research in order to improve quality of drug use. One component of this is the presentation and comparison of drug consumption statistics at international and other levels. Only medicinal substances (active ingredients) are included in the classification.

6. **Mandatory use of the nomenclature**

   a. **Has any country or organization made it mandatory to use the nomenclature for specific purposes?**

   In some countries the nomenclature is used for administrative purposes by regulatory authorities; e.g. in national drug catalogues. Implementation of the ATC classification system is a national decision. ATC codes are used by the European Medicines Agency.

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.**

   The structure of the ATC/DDD system is comprehensively described on our website [www.whocc.no](http://www.whocc.no) and in the publication *Guidelines for ATC classification and DDD assignment, 2011* (page 15). The publication is available as a pdf on the website.

8. **Are the terms used in the classification system generic i.e. non proprietary?**

   Yes.
9. Maintenance of the nomenclature system  
   a. How is the system maintained?  

   The WHO Centre is responsible for the maintenance of the ATC/DDD system. The system is updated annually.

   b. Please describe the process for creating or modifying terms in the system.  

   The procedures and data requirements for ATC/DDD assignment and alterations are described on our website www.who.cc and in the publication Guidelines for ATC classification and DDD assignment, 2011 (page 38). The publication is available as a pdf on the website.

   c. How is transparency ensured with regard to development and maintenance of the nomenclature?  

   All new ATC codes, DDDs or alterations decided at the two annual meetings of the WHO International Working Group are first published as temporary. Any interested part wishing to dispute this decision is invited to comment within a specified deadline after its publication. If there is an objection then the decision will be reconsidered at the next meeting.  
   An open session is held once a year in connection with the meeting of the WHO Working Group. It is held in the interest of transparency and consists of one hour and a half prior to the closed decision-making session of the meeting.

10. Different language versions of the nomenclature  
   a. How is the translation of terms and definitions managed?  

   The official languages (ref. point b) are handled by the WHO Centre.

   b. What language versions exist as of February 2011?  

   Official English and Spanish versions.

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

   None
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.

      Please refer to point 6a.

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.

      The WHO Centre has the intellectual property of the ATC classification.

   b. Is the system available as a package for integration into user IT systems (maintenance management, adverse event reporting, procurement....)?  

      [x] Yes  [ ] No

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

      No special conditions when the ATC system is integrated in computerized systems. Copying and distribution for commercial purposes is not allowed. Changing or manipulating the material is not allowed.

13. Interoperability

   Please specify compatibilities ensured and mappings to other nomenclatures maintained.
14. Model for sustainable financing
   a. How is the system financed? I.e. user fees, member fees, subscriptions, one off payments, open source?

   The WHO Centre is fully funded by the Norwegian government.
   See also below.

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

   No fee. However, we charge a handling fee for distribution of hard copies of our publications and electronic files. Please refer to order form on the website www.who.cc.no