Monographs on ARV and hepatitis medicines in The International Pharmacopoeia

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Technologies, Standards and Norms

World Health Organization
The International Pharmacopoeia

- contains analytical methods and specifications for
  - active pharmaceutical ingredients (API)
  - finished pharmaceutical products
  - radiopharmaceuticals

- focuses on medicines
  - Model List of Essential Medicines
  - Invitations to submit EOI for product evaluation to PQTm
  - WHO/UN specific disease programmes
The International Pharmacopoeia

• main areas of work
  – medicines for maternal, newborn, child and adolescent health
  – antimalarial medicines
  – antiviral medicines including antiretrovirals
  – antituberculosis medicines
  – medicines for tropical diseases

• part of WHO normative work

• based on the decision of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP)
The International Pharmacopoeia

- applies current international standards
  - comply with harmonized regulatory standards
  - focus on technical aspects most relevant for developing countries

- Ph.Int. aims at global applicability of its methods/specifications
  - for complex, technically demanding methods less sophisticated tests are given as an alternative, if equally satisfying

- rational use of International Chemical Reference substances (ICRS)
  - in situ preparation of impurities for identification purposes
  - quantification of impurities preferably by comparing their responses with the response of the parent compound in a diluted sample solution (together with the establishment of correction factors)
International Chemical Reference Substances (ICRS)

- primary reference standards
- established by European Directorate for the Quality of Medicines & HealthCare (EDQM)
- under the authority of WHO Expert Committee on Specifications for Pharmaceutical Preparations
Antiviral medicines including antiretrovirals

- 34 monographs on antiviral medicines
the development of new monographs follows our priority setting procedures:

- monographs for **essential medicines** listed in **EOI**
  - ...
  - 12th Invitation HIV/AIDS, hepatitis B/C medicines (September 2014)
- that have not yet been subject to a monograph published by another major pharmacopoeia
- will be developed with **HIGH PRIORITY**
- result of the survey performed in 2015
  - 17 antiviral medicines (incl. antiretrovirals) were identified for future elaboration with high priority
## Work Plan 2015/2016

### Monographs proposed for future elaboration

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Benefits of Public Standards / Ph. Int.

- public standards facilitate the production, registration, quality control and procurement of medicines
  - allow for an independent judgment on the quality of medicines
  - easy reference to acceptable quality standards (specifications, test methods and reference substances)
    - manufacturer has to demonstrate suitability of the tests
    - regulatory authorities have to approve the specifications
  - basis for regional/international harmonization
  - represent reference tests in case of doubt or dispute
  - applicable worldwide (The International Pharmacopoeia)
How to participate in the work of The International Pharmacopoeia?

- comments are welcome
  - on monographs and general texts under public consultation
  - already published monographs and general texts
  - web site with our current projects:

- donations are welcome
  - SRA approved test procedures and specifications
  - product samples
    - to verify test procedures
    - to back up specifications
  - candidate material to establish ICRS
Quality Assurance of Pharmaceuticals

- guidelines
  - development
  - production
  - distribution
  - inspection
  - quality control
  - other regulatory affaires
Thank you very much for your kind attention!