WHO Certification Scheme for Finished Pharmaceutical Products – Where are we today?

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Outline

- What is WHO certification Scheme?
- Evolution of the Scheme
- The current version of the Scheme
- Some limitations to the current Scheme
- Need for review of the Scheme
- Identified problems with the current Scheme
- Proposed recommendations for improvement
- Way forward
The WHO Certification Scheme

- An international voluntary agreement to provide assurance to countries participating in the Scheme
  - about the quality of pharmaceutical products moving in international commerce
- A tool developed in response to requests of WHO Member States
- A voluntary/non binding agreement between WHO Member States
- An information exchange mechanism on the quality of imported medicines
- Intended to give assurance to countries that are importing pharmaceutical products but have no national capacity to assess the safety, efficacy and quality of the medicines they import
- Is intended to facilitate availability and trade in pharmaceuticals by ensuring safety, efficacy and quality
In 1963 the World Health Assembly (WHA) passed resolution asking for:
- “examination of ways and means of ensuring that drugs exported from a producing country comply with drug control requirements which apply in that country for domestic use”

In 1969, the WHA adopted “Good Practices in the Manufacture and Quality Control of Drugs”:
- up-to-date list of manufacturers complying with GMP to be issued by governments
- batch certificate to be issued by health authorities of exporting countries
Evolution of the Scheme

- In 1975, the Scheme was revised to include
  - the registration status of the product in the exporting country
  - the GMP compliance of the responsible manufacturing unit

- In 1988, the 1975 version was expanded to include
  - Finished pharmaceutical products for human use
  - Veterinary products administered to food producing animals
  - Product information and labeling

- In 1992 the WHA proposed a revised version of the Scheme

- In 1997, after 5 years of testing, the current version was adopted
The Current Version

- Three types of certificates are issued under the current Scheme:
  - Certificate of a Pharmaceutical Product (CPP) – the primary Doc
    - Is used in connection with product registration
    - Provides information on: the product, GMP status of the manufacturing plant, the certifying authority
    - Assures that the product information accompanying the certificate is the same as the one approved by the certifying country
  - Model Batch Certificate of a Pharmaceutical Product - especially used for tenders
  - Model Statement of Licensing Status of Pharmaceutical Product(s) - especially used for tenders
Some limitations to the Scheme

- Rely on the honesty and competence of the issuing authorities
  - A certificate is as good as the certifying authority

- Requirements for MA differ in countries
  - More applies to generic drugs

- Counterfeit certificates a reality
  - Sample of fake logo from a website
Need for Review of the Scheme

- The 1999 ICDRA held in Berlin, Germany identified limitations inherent in the Scheme and recommended proposals for improvement.
- The WHO Expert Committee on Specifications for Pharmaceutical Preparations discussed proposals at various meetings i.e. 37th, 38th, 39th, 41st and 42nd further recommended for improvement of the Scheme.
- “WHO Consultation on new approaches and risk evaluation for manufacture of medicines” meeting held in June 2007.
- A Consultative meeting to discuss improvement of the WHO Certification Scheme held in Geneva from 22-24 July 2008
  - agreed on several recommendation for improvement on the Scheme to be further considered by ICDRA before submission to the 43rd Expert Committee.
Identified problems with the current Scheme

1. Issuing ("exporting") countries that do not fulfil the prerequisites required by the Certification Scheme issue certificates to support export
   - certificates are issued for products that are produced by manufacturers that do not comply with WHO GMP requirements
   - No self-assessment mechanism for NDRA

2. Countries not party to the Scheme issue certificates to support export of pharmaceutical products

3. Information on who released the batch for marketing is not disclosed in certificates issued by exporting countries

4. Member States issue certificates for products not under their jurisdiction
   - for products not authorized for marketing in their countries or not manufactured in their countries
5. The list of competent authorities is out of date
   – details of some authorities have changed
   – the current list of countries that participate in the Scheme in its present form is not readily available

6. The Scheme is formally at present directed to individual Member States
   – multistate organizations (e.g. European Medicines Agency (EMEA) and Organization of Eastern Caribbean States/Pharmaceutical Procurement Service (OECS/PPS)) also need to be able to operate within the Scheme
   – this applies to both issuing and receiving parties

7. There have been cases in which forged certificates have been supplied to competent authorities of importing countries

8. Some Member States issue other certificates such as free sale certificates contrary to the one recommended by WHO i.e. CPP

9. Importing countries require legalization of certificates, additional stamps, etc
**Recommended Actions**

**Actions by WHO**
- Inform Member States about the Scheme and its prerequisites, including monitoring the period of validity of the Scheme's membership
- Provide tools for DRA assessment
- Enhance international collaboration among DRAs and assist in capacity building
- Promotion of the Scheme – invitation to officially join the Scheme to countries that are issuing certificates but which are not party to the Scheme

**Actions by Member States**
- Improve on regulatory infrastructure by strengthening DRAs
- Include a requirement for a valid CPP of a country that is party to the Scheme when products are imported into the country
- Issue information regarding batch release
- Operate the scheme correctly
- Provide up to date information to WHO in response to circular letter to be sent by WHO
- Issuing ("exporting ") countries to develop secured certificates by using a watermark, hologram, or any other technology
Recommended Actions

- **Actions by WHO**
  - New information on batch release site should be introduced
  - Provide information to ensure that Member States do not issue certificates for products that are not under their jurisdiction
  - Send letter to member states, update the list of DRAs, publish and distribute the list
  - Revise the Scheme to allow for parties e.g. EMEA and OECS/PPS to join the Scheme in their respective official functions
  - Revise the current guidelines of the Scheme in order to strengthen it and to emphasize that legalization of the CPP is not required and in many instances is of little value

- **Actions by Member States**
  - Include a unique numbering system for ease of identification
  - Provide a mechanism for specimen of certificates
  - Avoid use of photocopies; only original CPP or identical copies clearly marked as "duplicate" can be accepted
  - Accepting ("importing") country authorities not to request or accept free sale certificates and issuing ("exporting") countries not to issue certificates other than those mentioned in the WHO Certification Scheme
  - Competent Authorities should not request for legalization of certificates
CONCLUSION

- The Consultative Group acknowledges the value of the Certification scheme and recognises its limitations
- Key areas of limitations have been identified and recommendations put forward for improvement
- Implementation of recommendations will strengthen the Scheme and improve compliance
Way Forward

- Participants of 13th ICDRA are urged to discuss, provide feedback and adopt proposed recommendations.

- Consultation Group report and ICDRA recommendations will be presented to 43rd WHO Expert Committee meeting in October 2008 with a view to adoption.
THANK YOU VERY MUCH