



NEW DEFINITION FOR "SUBSTANDARD MEDICINES"

Please address comments on this proposal, by 15 July 2010 to Dr S. Kopp, Medicines Quality Assurance Programme, World Health Organization, 1211 Geneva 27, Switzerland, fax: (+41 22) 791 4730 or e-mail: kopps@who.int with a copy to gaspardm@who.int and to bonnyw@who.int.

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**SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/10.344:
NEW DEFINITION FOR "SUBSTANDARD MEDICINES"**

Recommendation of the 44 th <i>WHO Expert Committee on Specifications for Pharmaceutical Preparations</i> to circulate new proposal for comments for definition preparation	12-16 October 2009
Deadline for comments on first mailing of proposal	10 April 2010
Summary of feedback	April-May 2010
Discussion of feedback during informal consultation on <i>Quality assurance systems, medicines and risk analysis</i> , Geneva	4-6 May 2010
A second discussion of feedback took place during the consultation on <i>Specifications for medicines and quality control laboratory issues</i> , Geneva	10-12 May 2010
Second proposal mailed for comments	May 2010
Collation of comments	July-August 2010
Presentation to 45 th <i>WHO Expert Committee on Specifications for Pharmaceutical Preparations</i>	18-22 October 2010
Any follow-up action, as needed	

New definition for "Substandard medicines"

In connection with the discussions during the WHO Governing Bodies' meetings, the terminology for "Substandard medicines" was raised during the forty-fourth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations.

Within the context of the work of this Expert Committee currently no officially adopted definition exists for "substandard medicines". As this question was frequently raised a "Question and Answer" section has been introduced on the WHO web site (<http://www.who.int/medicines/services/counterfeit/faqs/en/index.html>). On the basis of this the above-mentioned Expert Committee proposed to circulate a slightly modified proposal for a new definition.

During the following two WHO consultations which took place in Geneva: Quality assurance systems, medicines and risk analysis (4-6 May 2010); and Specifications for medicines and quality control laboratory issues (10-12 May), an extensive discussion took place on the feedback and additional input was also received from all experts who participated in the consultations. The following, revised definition is suggested:

What are substandard medicines?

New proposal

Each pharmaceutical product that a manufacturer produces has to comply with quality standards and specifications at release and throughout the product shelf-life required by the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable National Medicines Regulatory Authority before the product is authorized for marketing.

Substandard medicines are pharmaceutical products that do not meet their quality standards and specifications.
