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**GUIDE ON SUBMISSION OF DOCUMENTATION FOR  
PREQUALIFICATION OF INNOVATOR  
FINISHED PHARMACEUTICAL PRODUCTS  
APPROVED BY STRINGENT REGULATORY AUTHORITIES**

Please address comments on this proposal, by 1 October 2010. All comments should be sent to Dr. M. Stahl, Quality Assurance & Safety: Medicines, Essential Medicines and Pharmaceutical Policies, World Health Organization, 1211 Geneva 27, Switzerland, fax: (+41 22) 791 4730 or e-mail: stahlm@who.int.

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SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/10.383:  
GUIDE ON SUBMISSION OF DOCUMENTATION FOR PREQUALIFICATION OF  
INNOVATOR FINISHED PHARMACEUTICAL PRODUCTS APPROVED BY  
STRINGENT REGULATORY AUTHORITIES

Drafting of guideline by Theo Dekker and Birgit Schmauser	June/July 2010
Circulation of document for comments	July 2010
Consolidation of comments and review	August 2010
Circulation of revised draft for comments	August 2010
Presentation to the forty-fifth WHO Expert Committee on Specifications for Pharmaceutical Preparations	18-22 October 2010
Any further action as required	...

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51 **GUIDE ON SUBMISSION OF DOCUMENTATION FOR**  
52 **PREQUALIFICATION OF INNOVATOR**  
53 **FINISHED PHARMACEUTICAL PRODUCTS**  
54 **APPROVED BY STRINGENT REGULATORY AUTHORITIES<sup>1</sup>**

55 WHO recognizes the scientific evaluation of innovator finished pharmaceutical products  
56 (FPPs) by regulatory authorities, which apply similarly stringent standards for quality, safety  
57 and efficacy as those recommended by WHO. Where an applicant and a stringent regulatory  
58 authority (SRA) can agree to share the following information on an innovator FPP with WHO,  
59 WHO will consider such FPP for inclusion in the list of WHO prequalified products, as and  
60 when information about such a product becomes available to WHO and when the applicant in  
61 question expresses his or her interest in the product being prequalified by WHO.

62 The following should be submitted:

- 63 1. A covering letter, which should include:
  - 64 ○ a statement indicating that the information submitted is true and correct;
  - 65 ○ a statement confirming that for WHO prequalification the product, including  
66 composition/formulation, strength, specifications, packaging, etc., will at the time of  
67 submission be in all respects be the same as the product registered with the relevant  
68 SRA; and
  - 69 ○ the name of the person responsible for communication with WHO on any issues  
70 related to the product.
- 71 2. An original or certified copy of the current WHO-type Certificate of a Pharmaceutical  
72 Product issued and fully completed, including answers to each question, by the relevant  
73 SRA, together with the latest approved summary of product characteristics (SmPC), or an  
74 equivalent thereof, as well as the patient information leaflet (PIL) and labelling.
- 75 3. An assessment report issued by the relevant SRA. A publicly available scientific  
76 assessment report, such as the Scientific Discussion of the European Public Assessment  
77 Report (EPAR), issued by the relevant SRA is also acceptable.
- 78 4. A certified copy of the marketing authorization issued by the relevant SRA. If  
79 applicable a certified copy of the latest renewal of the marketing authorization should  
80 also be provided.
- 81 5. A list of the SRA-approved manufacturer(s) of the FPP, with the physical address of the  
82 manufacturing site(s) (and unit if applicable).
- 83 6. A list of the SRA-approved manufacturer(s) of the active pharmaceutical ingredient(s)  
84 (API) used in the manufacture of the FPP, with the physical address of the manufacturing  
85 site(s) (and unit if applicable).
- 86 7. A sample(s) of the product in market packing(s) should be provided with the submission to  
87 enable visual inspection thereof. The respective certificate of analysis should be attached.

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<sup>1</sup> Stringent regulatory authority (SRA): a regulatory authority which is: (a) a member of the International Conference on Harmonisation (ICH) (as specified on [www.ich.org](http://www.ich.org)); or (b) an ICH observer, being the European Free Trade Association (EFTA), as represented by Swiss Medic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time).

88 Please note that the submission must be in English, which includes authorized English  
89 translations of SmPC and other documents. These documents should be made available as  
90 hard copies and electronically. The SmPC and PIL should be submitted as Word files.

91 Variations to and renewal of the marketing authorization of a product that has been  
92 prequalified by WHO based on the approval by an SRA, remain the responsibility of the  
93 relevant SRA.

94 Once the product has been prequalified, WHO should be provided with a copy of the  
95 regulatory acceptance letter of any changes to the main characteristics of the product – such  
96 as the labelling for storage, the nature and contents of the container, the shelf-life, FPP or API  
97 manufacturing site(s), or any other relevant change to the product information – immediately  
98 after the variation has been approved by the relevant SRA. The main characteristics of the  
99 product will be listed in the Letter of Prequalification.

100 The preferred storage condition for WHO prequalified products is “do not store above 30°C”.  
101 If this is not indicated on the SmPC, PIL and labels of the innovator product, applicants are  
102 encouraged to apply for a variation in this respect with the relevant SRA. This could also be  
103 done after prequalification of the product.

104 **References:** Information and the full text of the relevant WHO documents can be found on  
105 the web site <http://who.int/prequal/>

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Draft for comment