Working document QAS/07.239
September 2007
RESTRICTED

World Health Organization

PROPOSAL FOR REVISION:

GOOD MANUFACTURING PRACTICES (GMP) FOR ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)

On the basis of a recommendation from the informal WHO consultation on new approaches and risk evaluation for manufacture of medicines, held in Geneva on 30 May-1 June 2007, we should be grateful to receive your feedback/comments as to whether you consider it appropriate for WHO to revise its current good manufacturing practices (GMP) for active pharmaceutical ingredients (APIs) (WHO good manufacturing practices: starting materials. In: *Quality Assurance of Pharmaceuticals. A compendium of guidelines and related materials, Volume 2, 2nd updated edition*. Geneva, World Health Organization, 2007, p. 188: http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html) with the principles laid out in the ICH GMP guide for APIs (http://www.ich.org/cache/compo/276-254-1.html).

Please send any comments you may have on this proposal to Dr S. Kopp, Quality Assurance Programme: kopps@who.int with a copy to locontea@who.int or fax: (41-22) 791 4730 by 30 November 2007. In the meantime this proposal will be discussed during the next meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations.

SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/07.239:

PROPOSAL FOR REVISION:

WHO GOOD MANUFACTURING PRACTICES (GMP) FOR ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)

Discussion during consultation on new approaches and risk evaluation for manufacture of medicines	30 May-1 June 2007
Mailing of proposal for revision for comments	October 2007
Presentation to WHO Expert Committee on Specifications for Pharmaceutical Preparations	15-19 October 2007
Follow-up action as required	October 2007 - …
Collation of comments	October-November 2007

PROPOSAL FOR REVISION:
WHO GOOD MANUFACTURING PRACTICES (GMP) FOR ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)

Discussions were held at an informal WHO consultation on new approaches and risk evaluation for manufacture of medicines in Geneva on 30 May-1 June 2007 as to whether the current WHO good manufacturing practices (GMP) for active pharmaceutical ingredients (APIs) should be revised to bring them into line with the ICH GMP guide for APIs (reference ICH Q7A).

Both texts can be found at the following web links:

- WHO good manufacturing practices (GMP) for active pharmaceutical ingredients (APIs). In: WHO good manufacturing practices: starting materials. In: *Quality Assurance of Pharmaceuticals. A compendium of guidelines and related materials, Volume 2, 2nd updated edition*. Geneva, World Health Organization, 2007, p. 188: http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html
- ICH GMP guide for APIs (ICH Q7A): http://www.ich.org/cache/compo/276-254-1.html).

In this respect a stepwise approach should be considered, including different scenarios.

It was recommended that the ICH Q7A guide should be adopted because:

- it has been adopted by numerous regulatory authorities worldwide;
- use of the guide has shown it has been well written; and
- many API manufacturers already comply with ICH guidelines.

The World Health Organization develops global guidelines, for which it must work through its own processes with confirmation by the WHO Legal Counsel.

During the above-mentioned consultation various approaches used in different countries were presented, e.g.

- Brazil: implements ICH Q7A, first listing of manufacturers followed by inspection;
- China: licensing of API manufacturers, revision of GMP is under way, and selected

items of ICH Q7A will be adopted for the parts not included in the main GMP text. Finalization is expected end 2007;

– India: APIs mostly produced for experts, and compliance with Schedule M (since 2005), with no change for API GMP requirements.

PROPOSED ACTIONS

1. Replace the current WHO GMP guide for APIs by the principles of ICH Q7A.

2. If the new approach as in 1. above is adopted a stepwise approach towards new GMP conditions is proposed.

   The implementation phase might take time and a transition phase would be necessary.

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