REVISIÓN DE LA GMP DE PRODUCTOS FÁRMACEUTICOS ESTERILIZABLES – UN PROYECTO JOINT DE EU, PIC/S, WHO

(Diciembre 2017)

DRAFT FOR COMMENT

Should you have any comments on the attached revision, please send these to Dr S. Kopp, Grupo Líder, Medicamentos Calidad de la Medicina, Tecnologías Nuevas y Normas (kopps@who.int) with a copy to Ms Xenia Finnerty (finnertyk@who.int) by 20 March 2018, or as described in the working document.

Our working documents will be sent out electronically only and will also be placed on the Medicines website for comment under “Current projects”. If you do not already receive our draft working documents please let us have your email address (foonyn@who.int) and we will add it to our electronic mailing list.

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Please send any request for permission to:

Dr Sabine Kopp, Grupo Líder, Medicamentos Calidad de la Medicina, Tecnologías Nuevas y Normas, Departamento de Medicamentos Esenciales y Productos de Salud, Organización Mundial de la Salud, CH-1211 Ginebra 27, Suiza. Teléfono: (41-22) 791 4730; correo electrónico: kopps@who.int.

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**SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/17.745:**

**REVISION OF WHO GMP FOR STERILE PHARMACEUTICAL PRODUCTS – A JOINT EU, PIC/S, WHO PROJECT**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Time Period</th>
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<tr>
<td>Communications and follow-up between PIC/S, EU and WHO, including official exchange of letters with the Chairperson of PIC/S exploring cooperation towards convergence on new guidance in data integrity and revision of GMP for sterile products. During the drafting process of the GMP text for sterile products, input was given by PQT-Inspection.</td>
<td>May 2015–November 2017</td>
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<tr>
<td>Recommendation during “GMP” meeting to work with PIC/S on the update and new guidance including, e.g. risk classification, data and record management practices and sterile products.</td>
<td>29 June–1 July 2015</td>
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<tr>
<td>Presentation to ECSPP for advice regarding convergence of new guidelines in the area of inspection and endorsement of collaboration.</td>
<td>17–21 October 2017</td>
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<tr>
<td>Joint public consultation phase on newly proposed update of the GMP text for sterile products</td>
<td>20 December 2017–20 March 2018</td>
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<tr>
<td>Compilation of comments and revision of draft based on feedback</td>
<td>Starting April 2018</td>
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<tr>
<td>Discussion at fifty-third meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations</td>
<td>October 2018</td>
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<tr>
<td>Any further action, as necessary</td>
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REVISION OF WHO GMP FOR STERILE PHARMACEUTICAL PRODUCTS –
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It is viewed that a common language would be beneficial to the authorities and the manufacturers, save resources and thus would ultimately benefit patients in having better access to quality medicines.

As an opportunity towards convergence in the area of GMP, WHO will therefore widely circulate the new proposal developed by EU and PIC/S with input from WHO to obtain feedback and comments on the newly suggested revision.

The manufacture of sterile medical products covers a wide range of product types (sterile active substance through to finished dosage form), batch sizes (single unit to multiple units), processes (from highly automated systems to manual processes), primary packaging materials and technologies (e.g. biotechnology, classical small molecule manufacturing and closed systems). This Annex provides general guidance that should be used for all sterile medical products and sterile active substances, via adaption, using the principles of quality risk management (QRM), to ensure that microbial, particulate and pyrogen contamination associated with microbes is prevented in the final product.

The WHO Secretariat is pleased to inform you that the current text is the first outcome of these efforts, the revision of the GMP for sterile products. The proposal is to replace the text: WHO good manufacturing practices for sterile pharmaceutical products published as Annex 6, WHO Technical Report Series, No. 961, 2011, by the text of the newly revised “EU-PIC/S GMP Annex 1 on the Manufacture of Sterile Medicinal Products” which has reached Step 2 (public consultation).

You are invited to provide your feedback and send your comments as detailed below. The consultation period will last 3 months and will run from 20 December 2017 to 20 March 2018.

We would like to draw your attention to the following:

The revised GMP text for sterile products has been prepared in cooperation with the EU, the European Medicines Agency (EMA), PIC/S and WHO in order to maintain global alignment of standards, achieving at the same time assurance for the highest quality. The document is subject to parallel public consultation by the European Commission (EC), PIC/S and WHO.

Key changes from the earlier text are:
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page 4

101 – introduction of new sections: scope, utilities, environmental and process-monitoring sections and glossary;
102 – introduction of the principles of quality risk management to allow for the inclusion of new technologies and innovative processes;
103 – restructuring to give more logical flow;
104 – addition of detail to provide further clarity.

The revised text is downloadable at the following link:

109 • Direct link to the consultation paper:
111 • Link to the consultation page:

117 It has been formatted with prescribed line and page numbers to support a joint international consultation within the EC, PIC/S and WHO.
118
119 In order to streamline the process, comments will be collected by the EC. We would appreciate if you could copy us. If you prefer to send the comments directly to us, using the attached WHO comments form, that is also acceptable.
120
121 Stakeholders should provide feedback using the enclosed EU template, sending it by email to: Sante-Pharmaceuticals-B4@ec.europa.eu and putting in the title: "Targeted Public Consultation – Revision of annex 1 of EU GMP Guide". It can also be sent by post to Directorate-General for Health and Food Safety, Unit SANTE B/4, BE-1049 Brussels. The subject line of the letter or email should contain the reference "Targeted Public Consultation – Revision of annex 1 of EU GMP Guide".
122
123 When submitting their response, stakeholders should include their name and email address and specify if they are responding as an individual or as a representative of an organization. If they represent an organization, they should indicate the name and category (company/business; public authority (local, regional, national, international); non-governmental organization (NGO); patient organization; other). If they represent a company, they should state whether they fall within the EU definition of a small and medium-sized enterprise (i.e., less than €50 million annual turnover and fewer than 250 employees).
125
126 For any additional queries in relation with this public consultation, the Directorate-General for Health and Food Safety – Unit B4 – Medical products: quality, safety, innovation, can be contacted at Sante-Pharmaceuticals-B4@ec.europa.eu.
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