



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 August 2016

Submission of comments on 'Implementation strategy of ICH Q3D guideline' (EMA/404489/2016)

Comments from:

Name of organisation or individual

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Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).



1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
<i>(To be completed by the Agency)</i>	<p>In December 2014 the ICH published the “Guideline for Elemental Impurities” and on July 1st 2016 the European Medicines Agency (EMA) published an “Implementation strategy of ICH Q3D Guideline” for consultation.</p> <p>ECHAMP, the European Coalition on Homeopathic and Anthroposophic Medicinal Products, assumes, that in the course of implementation it will be stated that Homeopathic and Anthroposophic Medicinal Products are out of the scope of the Guideline for the following reasons.</p> <p>The ICH guideline states in the “Scope”</p> <p><i>This guideline does not apply to herbal products.</i> Herbal products are defined in the Glossary as follows:</p> <p><i>“Herbal Products:</i></p>	<i>(To be completed by the Agency)</i>

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	<p><i>Medicinal products containing, exclusively, plant material and/or vegetable drug preparations as active ingredients. In some traditions, materials of inorganic or animal origin can also be present.”</i></p> <p>Therefore, as homeopathic and anthroposophic preparations derive from a special tradition, they should be out of the scope of ICH Q3D Guideline.</p> <p>With respect to the herbal materials, in the European Pharmacopoeia exist two monographs, one for “herbal drugs” and one for “herbal drugs for homeopathic preparations”. Both monographs have the same quality standards concerning the limits for heavy metals and the following paragraph, not concerned from ICH Q3D.</p> <table border="1" data-bbox="495 1091 1182 1374"> <tr> <td data-bbox="495 1091 837 1374"> <p>„Herbal drugs“ (1433)</p> <p>Heavy metals (2.4.27). Unless otherwise stated in an individual monograph or unless otherwise justified and authorised:</p> </td> <td data-bbox="837 1091 1182 1374"> <p>„Herbal drugs for homoeopathic preparations” (2045)</p> <p>Heavy metals (2.4.27). Unless otherwise stated in an individual monograph or unless otherwise justified and authorised:</p> </td> </tr> </table>	<p>„Herbal drugs“ (1433)</p> <p>Heavy metals (2.4.27). Unless otherwise stated in an individual monograph or unless otherwise justified and authorised:</p>	<p>„Herbal drugs for homoeopathic preparations” (2045)</p> <p>Heavy metals (2.4.27). Unless otherwise stated in an individual monograph or unless otherwise justified and authorised:</p>	
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	<ul style="list-style-type: none"> – <i>cadmium</i>: maximum 1.0 ppm; – <i>lead</i>: maximum 5.0 ppm; – <i>mercury</i>: maximum 0.1 ppm. <p>Where necessary, limits for other heavy metals may be required.</p> <p>Where necessary herbal drugs comply with other tests, such as the following, for example</p>	<ul style="list-style-type: none"> – <i>cadmium</i>: maximum 1.0 ppm; – <i>lead</i>: maximum 5.0 ppm; – <i>mercury</i>: maximum 0.1 ppm. <p>If justified by the nature or origin of the herbal drug or if required by the competent authority, suitable limits for the content of other heavy metals such as arsenic or nickel are defined.</p> <p>Where justified, the test for heavy metals may be performed on the mother tincture according to the requirements of the general monograph Mother tinctures for homeopathic preparations (2029).</p>	
	<p>Therefore the safety of herbal medicinal products and homeopathic medicinal products from plants concerning a contamination with heavy metals is</p>		

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	<p>assured in the same way and it is justified that herbal medicinal products (including homeopathic and anthroposophic products) are out of the scope of the ICH guideline. From the definition in the glossary it should be clear that other than plant material (e.g. material from animal or mineral origin), which are used traditionally, are also out of the scope of the guideline.</p> <p>To assure limits and methods for heavy metals it may be possible to implement the text of the monograph “Heavy metals” (2.4.8) in the monograph “Homoeopathic preparations” (1038). In individual monographs a cross reference may be given to the method and limits defined.</p>	

2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.