### QUESTIONS AND ANSWERS DOCUMENT ON THE QUALITY OF HOMEOPATHIC MEDICINAL PRODUCTS (Q 11-12)

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<td>Circulation of first draft in HMPWG Quality sub-working group for comments</td>
<td>21 September 2018</td>
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Impurities

Question 11

Are homeopathic medicinal products based on herbal substances/preparations out of scope of ICH Q3D (similar to herbal medicinal products)?

Answer:

Homeopathic medicinal products unlike herbal products are not excluded from the scope of ICH Q3D and according to the updated Ph. Eur. chapter 5.20, the European Pharmacopoeia (Ph. Eur.) applies the ICH Q3D guideline for elemental impurities in medicinal products to medicinal products with the exception of products for veterinary use, unlicensed preparations and products excluded from the scope of the guideline. Therefore the guideline Q3D applies to all homeopathic medicinal products for human use.

Question 12

What kind of data is expected for the risk assessment and control of elemental impurities in homeopathic medicinal product for human use?

Answer:

The guideline ICH Q3D presents a process to assess and control elemental impurities in the drug product. As the active substance of a homeopathic medicinal product for human use may not be the only potential source of elemental impurities for risk assessment, also any excipients used, manufacturing equipment as well as container closure systems have to be considered.

Concerning the active substance the source/origin and degree of dilution should be considered.

Concerning excipients further guidance on risk assessment can be found in the ‘Guideline on the formalized risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use’ (2015/C 95/02). Both guidelines should be applied taking into account the criticality of the respective drug product. If applicable same dosage forms - provided they contain the identical excipients and are manufactured at the same production site - could be grouped and assessed in a worst case scenario.

The summary of the risk assessment should be presented in module 3.2.P.5.5 or 3.2.P.5.6 of the dossier.