Readers' Tribune

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Quality aspects of homoeopathic preparations

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Homoeopathy was founded by Samuel Hahnemann in the 18th century. From the early beginnings in Germany and France, homoeopathy has been established in many countries all over the world. Two types of raw materials are mainly used in homoeopathy: i) chemically defined materials like elements, salts or minerals, and ii) fresh plant materials, which should be processed immediately. The production of homoeopathic preparations usually involves the production of the mother tincture and the 'potentisation', which is **not** simply dilution of the mother tincture or a chemical compound. By this defined procedure, the 'active principle' is transferred from the matter onto the final homoeopathic preparation. At this time we do not have an exhaustive explanation for this process with regard to the claimed efficacy. Also, neither analytical nor active markers are actually available justifying quantitative quality control of a homoeopathic preparation. In terms of general quality control it must be differentiated between the two types of starting materials mentioned above.

Pure elements, salts and minerals are typical starting materials of the first group. For the assessment of these compounds, the same standards as for the analysis of 'allopathic' chemicals can be applied. Usually, the starting material and the resulting most-concentrated homoeopathic preparation (MCHP) are described by physico-chemical methods (e.g., if applicable, melting point, density, crystal water, solubility) and ions are usually assessed by specific tests. Chemical impurities can be determined in a similar manner. Identity and purity must be shown.

What about the assay of chemically defined raw materials? For allopathic chemically defined substances with a distinct pharmacological activity, we usually can describe efficacy by a dose-response curve. Therefore, an assay is obligatory. In contrast, we do not have a dose-response curve in homoeopathy and, therefore, the concentration of a chemical compound is not directly related to the efficacy. Consequently, an assay using physico-chemical methods

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with the goal to quantify a chemical constituent of the raw material (or MCHP) is **not** necessary from a homoeopathic point of view. However, under general pharmaceutical quality aspects we can state that defined and pure compounds should be used for homoeopathic preparations. An assay is an appropriate method in order to determine required identity and purity. Consequently, an assay applied on chemically defined materials proves the purity of the used material but provides **no** information on efficacy of the resulting homoeopathic preparation.

For the second group of materials, preferably fresh plants should be used and processed in fresh state. In some justified exceptions, dried materials can also be used, but this will not be dealt with here. Plant materials are complex mixtures of many different substances. In most cases it is possible to prove the identity of the herbal raw material at the stage of the MCHP by thin-layer chromatography (TLC). This method is well established and appropriate for complex mixtures, also providing some semi-quantitative information.

Can an assay be justified for plant materials? For chemically defined materials, an assay can be used for purity control. In case of plant materials, we have a complex mixture of compounds and therefore an assay respecting only one compound or a group of compounds is not meaningful in terms of purity control. In conclusion, there is no justification to apply such an assay generally on a MCHP prepared from herbal raw materials.

Efficacy of a homoeopathic preparation must be related to the herbal material **as a whole**. Consequently, the amount of the total extract **as a whole** should be determined by a suitable 'surrogate' quality parameter. On mother tinctures, this can be done by determination of '**dry residue**' (HAB 2.2.6 or Ph. Eur. general method 2.8.16) and limits should be defined in each monograph of the Pharmacopoeia. There is no need to quantify further analytical markers, because there is no proof that they are related to efficacy of the final homoeopathic preparation in any way.

How to handle toxic plant material? According to Annex I of Directive 2001/83/EC, an assay is essential when the substance is toxic. However, this is not scientifically justified. 'Assay' in a pharmaceutical sense means that a lower and an upper limit have to be determined. It is assumed that the term 'assay' of the above-mentioned directive was used with the meaning 'quantitative determination'. But the terms 'assay' and 'quantitative determination' do **not** mean exactly the same thing. In the case of toxic compounds, we only need an **upper limit**, as is also the rule for contaminants. Therefore, a '**limit test**' is sufficient for safety reasons and the '**first safe dilution**' should be calculated from this limit. Annex I of Directive 2001/83/EC should be reworded in an appropriate manner. The monographs *Mother tinctures for homoeopathic preparations (2029)* and *Homoeopathic preparations (1038)*, as well as the 'Guide for the elaboration of monographs for homoeopathic preparations' should be also modified accordingly.