Internal Quality Standards for Homeopathic Medicinal Preparations

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The introduction to a draft of guidelines of GMP/GPP for Homeopathic Medicinal Products (HMP) (unfinished document from a Belgian homeopathic working party, 2002) says it well:

“Homeopathic and allopathic productions differ in some fundamental aspects, i.e.: high level of dilutions frequently used, use of a great variety of stocks (botanical, mineral, chemical and biological origin), a high number of batches, often small-sized because of the personalization of the homeopathic treatment, difficulty to perform the control of the active ingredients in the finished product, and in some cases specific production equipment.

In order to ensure the quality of homeopathic medicinal products it is essential that the specified manufacturing processes are followed precisely and that risks of cross-contamination are avoided. In view of the special properties of homeopathic medicinal products, analytical tests of the finished product have only limited value for the purpose of Quality control. It is often not possible to analyze extent infinitesimal doses commonly present in the finished product. Consequently, the specification and application of quality requirements for starting materials and the planning, monitoring and documentation of all manufacturing steps are particularly important to prevent any possible risk of cross contamination and intermixing and to ensure that the medicinal products are consistently of the quality intended.”

Quality requirements should be based on objective criteria and imply measurement against and comparison with accepted or ac-

ceptable standards. Discussion of internal quality requirements of HMP all comes down to discussion about these standards. Unfortunately, the relationship between these standards and their effects on homeopathic quality of the HMP is far from clear, and is difficult to show.

A number of standards and prescriptions are already available from traditional use or pharmacopoeia monographs. Together with other possible criteria of pharmaceutical quality of HMP, these standards will be discussed in depth. It will be shown that several standards should be replaced by more objective, more reproducible or more consistent ones in order to create a harmonized and universal set of quality requirements for HMP. Specific GMP and GPP guidelines for HMP should be based more and more on such a set of evidence-based requirements, rather than on traditional or instinctive expressions.

The presented data will cover most of the preparation and raw material aspects of HMP. Keywords in this story will be “reproducibility”, “traceability” and “safety”. Every aspect of preparing and delivering HMP will be evaluated against these criteria: internal quality of raw materials, excipients, packing materials, preparation and storage environmental conditions, methodology, equipment and galenics, use of informatics, elementary validation and documentation; these aspects have to be directed properly with only one final goal: respecting the legitimate demand of the patients and therapists for high quality homeopathic medicinal products.

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