

## GUEST EDITORIAL

# Homeopathic pathogenetic trials and provings: the need for harmonized guidelines

Homeopathic Pathogenetic Trials (HPT, synonym: proving) are considered a pillar of homeopathy.<sup>1</sup> The design is one of the first examples of systematic research on medicines, and it served as the theatre within which the first serious experiment with a placebo control group took place, in Nürnberg in 1835.<sup>2</sup>

But time goes on, and at the beginning of the 21st century, medicine, and so too homeopathy, is appraised by the contemporary standards of conventional science. Some may argue, that Hahnemann developed the proving design and can be considered the last word on it, but we have also witnessed a revival of provings some 25 years ago, with a synchronous effort to formulate more explicit rules for the conduct of provings.<sup>3,4</sup> The latest systematic review of the design elements applied in provings covered the period between 1945 and 1995.<sup>5</sup> Recent developments in provings suggest that even Hahnemann can be subjected to appropriate updating.<sup>6</sup> Time for reconsideration!

Since 1990, in parallel with a diversification of analytical techniques in the therapeutic practice of homeopathy, e.g. by Herscu, Mangialavori, Sankaran, Scholten and others, we have seen a diversification of proving procedures, e.g. by Becker, Dam, Sherr and Tuminello. Notwithstanding the methodological expansion of ideas, the clinical verification of proving data remains the ultimate yardstick of the validity of these new developments. Hering is said to have estimated that the average time between a proving and a fully established *Materia Medica* picture was 30 years, and in our view there is no reason for this interval to have changed since. There are several drivers of this reality, one of them being the quality of the proving procedure itself.

## Validity

So we are at a crossroads: Most of us think of a proving as an experimental procedure validated by 200 years of experience. This indeed appears to be true for the excellent safety record of provings. However, the validation of the clinical reliability of the proving procedure itself is dependent on the results of the clinical verification phase during the years that follow publication of the proving, with many factors unrelated to proving quality affecting the outcome. For this reason, concepts from conventional medical

research are being applied to the thinking about the validity of provings to compensate for the long duration between proving and completed clinical verification, both by some contemporary proving conductors,<sup>4,7</sup> as well as, to an increasing degree, by regulatory institutions.<sup>8</sup>

Many of these transposed concepts are certainly worthy of our consideration, but the usefulness of most of these concepts to provings has not been rigorously evaluated and researched. The optimal duration of the observation phase, the efficiency of a placebo control group and the ideal number of volunteers are obvious examples of these.

The *status quo* described above provides reasons to formulate best practices for the conduct of provings in the format of a set of guidelines. These guidelines should take cognizance of the reality of the existing regulatory frameworks and the reality of limited resources and opportunities for homeopathic research. Homeopathic theory and two centuries of experience should be the basis upon which we proceed, whilst the added value of modern methodological insights should be incorporated where appropriate and in keeping with a homeopathic perspective. Differences between homeopathic considerations on the one hand, and the official or universal (such as the Helsinki Declaration) regulations on the other and, where these exist, need to be acknowledged. We believe that many of them can be solved in a satisfactory manner. In this way, the aim to provide guidance to proving conductors, scientists, educators, regulators, industry and to other stakeholders, in our opinion, is best served.

## Call for comments

The *Liga Medicorum Homeopathica Internationalis* (LMHI) and the European Committee for Homeopathy (ECH) are harmonizing their proving guidelines into a common global document, in accordance with all the aforementioned. These guidelines describe all relevant topics that together must lead to a useful proving: Safety of volunteers, potencies and doses, inclusion and exclusion criteria both for volunteers and symptoms, duration of each phase of a proving, how many provers to recruit, what to record for each symptom, such as information that enables to decide if a symptom is likely to be caused by the test remedy, qualifications of coordinator and supervisors, the supervision process, placebo control, definition of characteristic symptom, confidentiality issues, and other topics.

Examples of differences between LMHI and ECH Guidelines concern topics such as the appropriateness of a placebo control group, the criteria that define the duration of the observation period, the ideal number of volunteers, the potencies to be used.

Although LMHI and ECH together represent homeopathic doctors worldwide, provings are of general interest for many more stakeholders in homeopathy, such as professional homeopaths, scientists, educators, regulators, ethical boards, industry, volunteers and patients.

We invite readers to contribute their comments on a range of details on the website that we have established for this project. You can e-mail [Subscribe@proving-guidelines-LMHI-ECH.org](mailto:Subscribe@proving-guidelines-LMHI-ECH.org) to receive an account and instructions.

## References

- 1 Walach H. The pillar of homoeopathy. Homoeopathic drug provings in a scientific framework. *Br Homeopath J* 1996; **86**: 219.
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- 8 Homeopathic Pharmacopoeia Convention of the United States (HPCUS). *HPCUS Proving Guidelines*; 2013.

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