ESSAY: Untested stem cell therapies

Quacks and charlatans: Age-old adversaries, but no less dangerous!

by Ira Herrmann

The process for developing new drugs and treatment methods is usually lengthy and full of obstacles. In the interests of effectiveness and safety, research and validation are conducted in a way that allows them to be as internationally comparable as possible. By now, guidelines and standards on the manufacturing and testing of drugs and pharmaceutical products are subject to international regulations in order to ensure patient safety and the efficacy of new medicines. Nevertheless, some forms of treatment that are well established and fully approved today began life in "compassionate use" – i.e. outside controlled clinical studies. And there have always been those who have tried to bypass the lengthy clinical development stage so as to be able to offer new therapies faster. This secures them, at best, a shady chapter in medical history, and usually the only tangible results are their fatter wallets.

Regardless of the drug or procedure that needs to be tested, one of the constant challenges that developers and practitioners face is how to deal with patient expectations. This is a particularly heavy burden when it comes to treating patients with very limited options and, in the worst cases, low chances of survival. For some years now, certain providers have been taking advantage of the hype surrounding stem cells as some kind of miracle cure and exploiting the fact that there are currently no stem cell-based treatments and products available and that the legal framework for the use of stem cells is often sketchy. Yet the history of medicine has always been full of "miracle healers" and charlatans. What's more, loopholes in medical law are often knowingly accepted in the interests of freedom of therapy and the development of new fields.

So why is there such a fuss about offering unproven stem cell therapies? And is the reaction justified?

- Due to their special properties, stem cells have the potential to treat a wide variety of illnesses – including many widespread and/or currently incurable diseases. This potential creates expectations that science is unable to meet in such a short period of time (just as a reminder: the first isolation of human embryonic stem cells was achieved in 1998).

- Stem cell research is a young discipline with its roots in developmental and cell biology. Today, however, it needs knowledge input from other natural scientists, engineers and, above all, representatives of various medical and clinical disciplines. It has thus become a truly interdisciplinary scientific field. However, this interdisciplinarity also requires the establishment of a common language when discussing basics, methods and aims.

- The approval of stem cell-based therapies is subject to new and very particular legal conditions. So far, only very few authorizations have been granted worldwide, giving us very few precedents to learn from. In Europe, for instance, only six products have been approved under the EU Regulation on advanced therapy medicinal products (ATMPs), which came into force in 2008. So there is also still (pioneering) work to be carried out in this area by developers and regulatory authorities.

So we see that stem cell research is a young biomedical discipline that has great potential and capacity for innovation, but that is confronted with extreme expectations. These expectations need to be addressed and worked through in line with the principles of good scientific practice. It is advisable, therefore, to conduct dialogue with all stakeholders – dialogue that also allows for the public criticism of providers of unproven stem cell-based treatments. Not because quacks and charlatans are a new phenomenon, of course, but because stem cell research is such an important new field with the potential to solve the problems of an ageing society.