Advanced Therapy Medicinal Products – a Multiple Challenge

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The passage of European Union Regulation 1394/2007/EC [1] on Advanced Therapy Medicinal Products (ATMPs) complements the European Community code relating to medicinal products for human use [2, 3]. This regulation is thus immediately valid in all member states of the European Union for gene therapeutics, somatic cellular therapeutics, and tissue engineering products. The latter include biotechnologically processed cells or tissues as well as products which have properties suitable for the regeneration, restoration or use of human tissue, or are used for this purpose or administered to humans. This issue focuses on the outcome of research dealing with musculoskeletal tissues as well as aspects of cell culture systems.

The development of ATMPs is often characterized by their experimental character and takes place in university clinics or smaller pharmaceutical companies. Individual production in often small quantities for the treatment of extremely serious diseases has so far resulted in the near total absence of the traditional pharmaceutical industry in this area. Since 2009 a centralized authorization procedure has applied for all European member states in order to evaluate the safety, effectiveness, and quality of ATMPs. Contrary to most medicines, which may be authorized in individual states within the EU, ATMPs have to be authorized through the centralized European Medicines Agency (EMA) which governs all of Europe. Authorization documents are evaluated by the Committee for Advanced Therapies (CAT) that was recently founded for this purpose.

In the introductory paper Flory and Reinhard [4] present the current state of affairs in the field of ATMPs. A well-structured insight is given into authorization procedures as well as the classification of an individual ATMP. Smith et al. [5] complement this with a commentary which looks at the current situation of ATMPs as well as their future orientation from the point of view of producers and users. The following original papers point out different aspects of research activities in the

field of ATMPs. Witzeneder et al. [6] report on human-derived alternatives to fetal bovine serum in cell culture systems. In this study human serum and thrombocyte lysate were used as alternative solutions which might open up interesting perspectives also for transfusion medicine facilities. A short communication by the same research group [7] discusses the protein pattern of these human alternatives with regard to methodology and suggests further lines of research. In view of the current discussion concerning vCJD risk [8], such papers are of great relevance. Krüger et al. [9] examined platelet-rich plasma gained through apheresis with respect to bioactive factors and evaluate its suitability for the use in cartilage regeneration. The detected chondrogenic growth factors may support cartilage repair by inducing cell differentiation and cartilage matrix formation. Kadow-Romacker et al. [10] make a contribution in the area of cellular bone regeneration by showing that insignificant frequency changes in the stimulation of osteoblast- and osteoclast-like cells may already provoke significant changes in the degree of differentiation. Von Roth et al. [11] report about the improvement of the contraction forces in injured skeletal muscles after autologous mesenchymal stroma cell transplantation. An interesting result in this connection is a slow to fast fiber shift. The review by Wiczorek et al. [12] gives a comprehensive and well-commented picture of the current state of knowledge in the field of genetically modified T cells for the treatment of malignant diseases. This paper examines another area of ATMPs, i.e., gene therapeutics. Finally, Kalus et al. [13] pick up anew the topic of postmortal infection diagnosis and present their results for the validation of serological testing for anti-*Treponema pallidum* from postmortem blood on the Siemens-BEP-III automatic system.

The editors of this special topic would be happy if this small but interesting selection of papers presented here arouses the interest in the reader to learn more about the promising and expanding field of ATMPs.

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