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Editorial

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ATMPs: New Challenge for Transfusion Services

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Advanced therapy medicinal products (ATMPs) are medicines for human use that are based on genes, tissues, or cells. They are classified into three main types: gene therapy medicines (GTP, P stands for "Product"), somatic-cell therapy medicines, and tissue-engineered medicines [1]. Currently, the Committee for Advanced Therapies of the European Medicines Agency (EMA) lists 64 ATMPs and their subcategories [2], of which 13 ATMPs, including 10 gene-modified therapeutics, two tissue products, and one cell-based medicinal product are recognized by the EMA [3]. EMA also provides regulatory and scientific support to help academics develop medicines.

In a more restrictive sense, blood products, derivatives of blood components, microbiome preparations, and some vaccines constitute medicinal products which are prepared from biological material by compulsory approval processes. These biological therapeutics lack standardized product parameters which precludes product license. Therefore, the regulatory authority requires accreditation of processes for the manufacture of these non-standardized medicinal products (NSMP). According to the Swiss authority, labile blood products like red cell concentrate, fresh frozen plasma for transfusion, and platelet concentrate as well as platelet-rich plasma (PRP), platelet-rich fibrinogen (PRF), autologous-conditioned plasma (ACP), and autologous serum eye drops (ASD) constitute NSMPs [4]. This may be differently regulated in other European countries.

This issue of TMH focuses on some NSMPs currently applied in advanced patient care. In the absence of large multicenter, controlled trials, blood products and also NSMPs are used based on personal experience and intuitive practice. Unfortunately, only a few experts in the field agreed to contribute in writing on the largely debated ATMPs and NSMPs. Nevertheless, we welcome the articles in this issue of TMH on these subjects. May they inspire further discussions in promoting ATMPs and NSMPs.

The article by Priesner et al. [5] focuses on the current challenge in the provision of ATMPs for individual patient care. Although clinicians as well as transfusion medicine specialists intend to treat patients via well-determined protocols, they often lack scientific, technological, and financial resources to guarantee cell-based therapies. Moreover, regulatory issues may overstrain the available infrastructure and logistic capacities of public health services. Sophisticated patient care using biotechnology tools requires to cooperate with modern biotechnology stakeholders. Monetary, as well as reputational issues, may become driving forces in the field. However, practical issues such as recruiting suitable patients, assuring sample preparation, and issuing final products for therapeutic use constitute indispensable steps in the supply chain of ATMPs. As suggested by Priesner and Hildebrandt [5], regional ATMP competence centers may fill the gap between industry, regulatory authorities, and health care providers by the provision of technical, personnel, and infrastructure resources. Once licensed the regional ATMP competence centers may therefore become central players for the development of the field.

The review on the use of PRP in plastic surgery by Hasiba-Pappas et al. [6] summarizes the data of 50 published studies assessing the clinical efficacy of PRP in craniofascial and hand surgery as well as in reconstructive sur-

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gery, burn injury, and as adjuvant in fat grafting. Diversity of preparation processes of PRP as well as heterogeneity in study design preclude firm conclusions on the beneficial effects of PRP. Unfortunately, more than 90% of identified studies miss sufficient quality to be included in the review underlining the need for well-designed prospective studies in this field.

Transfusion of autologous red blood cells by cell-saving technology is broadly accepted in nonmalignant surgery. The technique has an important impact on preventing homologous blood transfusions. However, concerns have been raised about its use in tumor surgery since retransfusion of tumor cells may promote metastatic propagation of disease. The updated review by Frietsch et al. [7] summarizes the data on the subject published to date. Only 34 studies out of 762 publications fulfilled the quality parameters to be included in the review. Although the impact of leucodepletion may diminish the risk to transfuse tumor cells the scientific data are missing. Nevertheless, the outcome of patients treated with autologous cell saving is not different from patients receiving homologous blood transfusions. Therefore, autologous cell saving in tumor patients seems advisable, especially if homologous transfusions can be spared. But it is highly desirable to generate data in larger, prospective randomized trials with respect to the usage of autologous red blood cells harvested by cell saving methods during surgery of patients with malignant tumor diagnosis.

Conflict of Interest Statement

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