Rik J Scheper: European Regulations on cell therapy, going too far?

Nancy Q. Zhong

Editorial Office, Chinese Clinical Oncology, China

Corresponding to: Nancy Q. Zhong. Editorial Office, Chinese Clinical Oncology, China. Email: editor@thecco.net.

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Introduction

Rik J. Scheper, Ph.D., is an immunologist and experimental pathologist in the Department of Pathology of VUmc in Amsterdam (*Figure 1*). Currently, after his nominal retirement in 2010, Rik J Scheper continues as an advisor and academic project and thesis promotor in the Departments of Pathology, Medical Oncology, and Dermatology of the VU University Medical Center, next to his contributions to two offspin companies focusing on advanced tissue medicinal products, DCPrime BV (tumor vaccine development) and ASkin BV (autologous cultured skin grafts).

In the following interview, Dr. Scheper would give us a some comments on the regulations of cell therapy in Europe as presented at the last CSCO meeting in Beijing.

Figure 1 Dr. Rik J Scheper, being interviewed by DXY reporter during the Chinese Society of Clinical Oncology (CSCO)

Interview

CCO Editor: *What has been changed through the past few decades in cell therapy regulations in Europe and what challenges the progress most?*

Dr. Scheper: What has changed particularly is the immense increase in knowledge about cancer and the development of multiple novel immunotherapeutic options in this widespread and threatening disease. And in connection to that, exciting technological advances have been made offering major improvements not only in early detection and prevention of cancer but also in the production of novel drugs and tumor vaccines. On the regulatory side, it has also led to a sharp increase in preclinical and clinical trials testing new products. Unfortunately, like classical chemotherapeutic drugs also novel drugs, even including more personalized or targeted drugs, were also frequently found to show undesirable side effects including death. In the present risk-avoiding society this has led to tightened regulations which currently actually function as a serious counter-acting force in the development of novel anti-cancer therapies. Patients with a poor prognosis may not really be helped much by such tight rules. So, today regulations and regulatory issues have exploded and create serious delays and cost-explosions in further developments in this field.

CCO Editor: *What challenges the development of cell therapy regulation in Europe along the way? What are the major differences of cell therapy regulations between Europe and China?*

Dr. Scheper: I think what challenges the development of novel cell therapies most is the tightened registration of the cell therapy regulations, in particular referring to the

Advanced Tissue Medicinal Product (ATMP) regulation (EC No 1394/2007). Actually, the European Medical Authority (Agency) EMA has recently installed committees (Committee for Advanced Therapies -CAT- working parties) to review the procedures and scientific basis for improvements in the procedures involved. EMA also makes several attempts to maximally reduce the regulatory hurdle by providing very clear information on all procedures in an excellent website, and providing free consultancies to all those who are considering clinical trials and/or registration (http://www.ema.europa.eu/).

I do not know too much about current Chinese regulations in this field but I feel regulations in China are still relatively easy. But I understand that China is preparing to adopt similar regulations as those in the United States and/or Europe. Maybe China should focus first on the American regulations since I feel that the European regulations went too far and currently are too tight. Let's take tumor vaccines for cancer patients as an example. Most of these are designed for patients with a poor prognosis anyway, and rules could be more lenient than when developing vaccines for healthy babies or young people. At this stage for experimental drugs there is a so-called Hospital Exemption Regulation in place, which allows medical doctors to use new experimental drugs or cellular therapies on an individual patient basis. In that case formal proof of activity is not required but still production requirements are still so tough that few University Hospital settings comply with the rules. This might resemble the situation with Chinese Traditional Medicine preparations in China most of which have no proven activity but may still be approved by the State Food and Drug Administration and are used by many doctors.

CCO Editor: *As a Co-founder of DCPrime, what are the major advantages of DC-based vaccines compared to other types of therapeutic vaccines?*

Dr. Scheper: In multiple studies in the past years immunological dendritic cells have been identified as the most outstanding antigen-presenting cells and thus can provide the best basis for cellular anti-cancer vaccines. The advantage of the dendritic cell line developed by our team is that the same vaccine can be used for most of the patients and thus allows for a so-called 'off-the-shelf- treatment'. It has been approved by EMA for early clinical trials particularly in patients with acute myeloid leukemia.

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