Position statement della World Marrow Donor Association (WMDA) sull'uso dei fattori di crescita biosimilari per la mobilizzazione delle CSE in donatori sani e la posizione di SIMTI.

In merito all'uso dei fattori di crescita emopoietici "biosimilari" per la mobilizzazione delle CSE nel sangue periferico in donatori sani, familiari e non familiari, la SIMTI trova pieno accordo con IBMDR (Italian Bone Marrow Donor Registry) nel condividere quanto espresso dal WMDA (vedi documento "20110706-CLWG-STAT-Biosimilar") relativamente all'utilizzo dei fattori di crescita biosimilari:

"As the efficacy for mobilisation is extrapolated, with little safety analysis and no long-term follow-up, the WMDA recommends that biosimilars must not be used for mobilisation in normal donors unless the donor is followed on a study addressing this question. Only when comprehensive data to confirm safety and efficacy is available should use of G-CSF biosimilars be considered routine"

Si raccomanda dunque che per la mobilizzazione delle CSE nel sangue periferico in donatori sani siano utilizzate le formulazioni del fattore di crescita emopoietico G-CSF rilasciate e presenti in commercio come "farmaci originatori" fin dagli anni '90, di cui è consolidato l'uso nei donatori sani e di cui sono noti e disponibili i dati di follow-up, e non si utilizzino a tale scopo i prodotti "biosimilari".

Ref:

Concerns about the use of biosimilar granulocyte colony-stimulating factors for the mobilization of stem cells in normal donors: position of the World Marrow Donor Association

Bronwen E. Shaw,1,2 Dennis L. Confer,3 William Y. Hwang,4,5,6 Derwood H. Pamphilon,7 and Michael A. Pulsipher8,9

1Anthony Nolan, UCL Cancer Centre, London, UK; 2Haemato-oncology, Royal Marsden NHS Foundation Trust, London, UK; National Marrow Donor Program, Minneapolis, MN USA; 4Singapore General Hospital, Singapore; 5Duke-NUS Graduate Medical School, Singapore; 6Singapore Cord Blood Bank, Singapore; 7NHS Blood and Transplant Bristol Centre, Bristol, UK; 8Division of Hematology, Blood and Marrow Transplantation, University of Utah, USA; 9Primary Children's Medical Center, Salt Lake City, Utah, USA. E-mail: bshaw@doctors.org.uk

doi:10.3324/haematol.2011.045740

Concerns about the use of biosimilars G-CSF
Document Type: Position Statement WG/Committee: CLWG
World Document Reference: 20110706-CLWG-STAT-Biosimilar Other (specify):
Marrow Version: 1 Approved by: Board
Donor Drafting Date: Approval date: 2011-04-01
Association Status Public

Concerns about the use of Biosimilar Granulocyte Colony Stimulating Factors for the mobilization of stem cells in normal donors. Position of the World Marrow Donor Association

Recombinant Granulocyte Colony Stimulating Factor (G-CSF) is routinely used for the mobilisation of haematopoietic stem cells (HSC) from the bone marrow into peripheral blood for collection by apheresis for transplantation. Since the late 1990s, HSC collection from related and unrelated healthy donors has been routine in Europe and North America. Two branded forms of G-CSF have been marketed since the early 1990s and there is extensive data concerning their use in normal donors.

Since 2002, the World Marrow Donor Association (WMDA) has maintained a centralised database collecting both short and long-term adverse events in unrelated donors receiving G-CSF. Recently, G-CSF biosimilar agents have become available. Biosimilars can be licensed based on data showing comparability to the reference product for the primary indication. Here we present the available evidence for the licensing of biosimilar G-CSF for mobilisation of HSC in Europe. As the efficacy for mobilisation is extrapolated, with little safety analysis and no long-term follow-up, the WMDA recommends that biosimilars must not be used for mobilisation in normal donors unless the donor is followed on a study addressing this question. Only when comprehensive data to confirm safety and efficacy is available should use of G-CSF biosimilars be considered routine.