

	Use of biosimilar filgrastims			
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Recommendation for recombinant human G-CSF (G-CSF) that stem cell donor registries can use- The use of biosimilar G-CSF

Normal individuals are at risk for developing cancer, including leukemia, lymphoma or other blood diseases throughout their lifetime. G-CSF stimulates normal blood cell growth. In some patients with cancer or abnormal blood cells, it has also been shown to stimulate leukemic blood cells. Studies following large numbers of unrelated donors have shown that the risk of developing cancer within several years after the use of G-CSF is not increased compared to donors not receiving G-CSF.

These large studies on donors were performed using the types of G-CSF called Neupogen (filgrastim, Amgen) or Granocyte (lenograstim, Chugai). Other types of G-CSF called biosimilars (or follow-on biologics) have minor differences.

Based on a recent survey of forty-two organisations performed by the Medical Working Group of the WMDA, and a review of the literature (publication pending), the 2012 WMDA recommendation on the use of biosimilar filgrastims has been revised as follows:

- Stem cell donor registries or their affiliated organisations may use filgrastim biosimilars, provided that they are approved by national and/or regional agencies *for CD34-positive cell mobilisation in healthy donors* or equivalent wording. Donors on approved research protocols are exempt from this restriction.
- If a new filgrastim biosimilar is used by a registry or its affiliated organisation, the registry should have a policy to continue to follow donors to identify any adverse effect possibly caused by the biosimilar.
- Stem cell donor registries must report adverse events and reactions (SEAR and SPEAR) as per usual practice, in addition registries MUST record the specific brand of mobilising agent in the S(P)EAR report.

Currently, WMDA cannot recommend the routine use of GM-CSF, plerixafor or similar mobilizing agents, but recognises that there may be situations where their use is appropriate per individual situations.