AISBL European Haemophilia Consortium (EHC) No. 887.106.966
Rue de l'Industrie/ Nijverheidsstraat 10, 1000 Brussels, Belgium
Tel. +32 (0) 2 894 23 70; Email: office@ehc.eu; Website: www.ehc.eu

Brussels, 2 November 2016

European Commission
DG Health and Food Safety
Unit B5 "Medicines – policy, authorisation and monitoring"
B-1049 Brussels (Belgium)

Subject: **EHC Response to the Concept of 'similar medicinal product' in the context of the Orphan Legislation: Adaptation to technical progress**

Dear Madam, Dear Sir,

The European Haemophilia Consortium (EHC) is an umbrella patient organisation representing 45 patient groups in Europe for people with haemophilia and other rare and congenital bleeding disorders. The EHC welcomes the opportunity to comment on the European Commission's 'Concept paper on 'similar medicinal product' in the context of the orphan legislation.'

The EHC would like to propose the addition of the following sentence at line 73 (pg. 3 – i.e. at the end of the second bullet point): "*In addition, if two substances differing in glycosylation patterns show different immunogenicity, these substances should be considered non-similar.*"

Immunogenicity to replacement therapy is one of the biggest issues in the modern treatment of haemophilia. In fact inhibitor development can affect up to 30 per cent of patients being exposed to treatment and has serious consequences on both the physical and psychosocial wellbeing of patients and their families.

Currently, we do not yet fully understand to which extent glycosylation profiles influence immunogenicity of clotting factors. The EHC believes that the addition of this sentence would accurately reflect the fact that apparently similar products may have different immunogenicity profiles, which ultimately impact patients' safety.

The EHC office remains at your disposal for any further additional information that you may need.

Yours sincerely,

Amanda Bok

EHC CEO