

ABSTRACT FORM ECAT SYMPOSIUM 8 – 9 NOVEMBER 2018

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Title:

Potency Labelling of extended half-life FVIII and FIX products

Abstract:

Coagulation factors are biologicals and accurate estimation of their activity relies on comparison with appropriate potency reference standards. The first International Standards (IS) for potency measurement of FVIII and FIX were established in the early 1970s, These IS were prepared with plasma derived concentrates and served well to ensure the consistency of production and potency labelling in International Units (IU) of plasma derived therapeutics available at the time. Potency labelling in IU also allowed the interchangeability of products for prophylaxis and treatment of haemophilic patients. Extended half-life (EHL) products are now available as alternatives to plasma derived products. It is clear the EHL products which are manufactured by recombinant technology, with structural modification to prolong the half-life of the products have distinct advantages over the conventional plasma derived products. However, assay discrepancies presents a complex challenge for potency labelling of these products. Recommendations from the regulators such as the European Medicines Agency (EMA) and the Scientific and Standardization Committee (SSC) of the International Society on Thrombosis and Haemostasis (ISTH) provide some guidance that aid global harmonisation of potency labelling of EHL products. However, due to their individual characteristics, the route for potency labelling for each product still require independent consideration.