Grounds for one additional renewal

The CHMP recommend an additional five-year renewal based on the following pharmacovigilance grounds: the clinical experience with the product in the designated indication has been very limited in the EU during the first 5-year period of marketing authorisation. Indeed, there has been a limited exposure due to a recent and limited marketing of the product (launched in the EU only in August 2011 and marketed in only few Member States). In addition, results of the post-authorisation studies to investigate the long term safety and efficacy of Opgenra and also investigate the actual drug utilisation in 'real life' are needed to further characterise the safety and efficacy profile.