Proficiency Testing Scheme Study on Hepatitis C Virus Testing of Plasma Pools by Nucleic Acid Amplification Techniques

Organising Institution: European Directorate for the Quality of Medicines & HealthCare (EDQM)

Since 1\textsuperscript{st} July 1999, in order to comply with the European Pharmacopoeia monograph “\textit{Human Plasma for Fractionation}” (0853) plasma pools have to be tested by the manufacturers for Hepatitis C virus (HCV) RNA by Nucleic Acid Amplification Technique (NAT) and found negative.

As laid down in Article 114.2 of Council Directive 2001/83/EC (as amended by Directive 2004/27/EC), and in accordance with the relevant guidelines for Official Control Authority Batch Release for blood products, plasma pools are re-tested for the presence of HCV RNA using NAT by Official Medicines Control Laboratories (OMCLs).

Participation in external quality assessment programmes such as proficiency studies has been recognised as an important factor for Quality Assurance as prescribed in the Ph. Eur. general method 2.6.21 "Nucleic acid amplification techniques".

From 1999 to 2003 PTS studies on HCV RNA NAT were run twice a year for OMCLs by the EDQM. In 2003, it was decided at the annual OMCL meeting in Warsaw to reduce the frequency to one study per year. Furthermore, it was decided to allow participation of plasma product manufacturers in subsequent Proficiency Testing Scheme (PTS) studies.

PTSs are open to OMCLs and manufacturers of plasma derived products available on the European market. Participation is on a voluntary basis, subsequent to prior registration.

Each panel of test samples is usually composed of 20 coded vials. Dilution series of HCV RNA preparations of different genotypes, as well as negative samples are included in each panel.

Participants are requested to test the samples of the panel in a single run in their established method and report results to EDQM. To check that the HCV RNA titres of the samples are in accordance with the expected values, one coded pilot panel for each study (coding different from final panel) are tested by the laboratory of the Scientific Advisor, prior to distribution to the participants.