ANNEX 1 – More information about the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe (EDQM / CoE)

The CoE is an intergovernmental pan-European organisation composed of 47 Member States (MS) whose main objective is to promote and implement human rights, democracy and the rule of law in Europe. The EDQM, a Directorate of the CoE and partial agreement, based on the Convention on the elaboration of a European Pharmacopoeia, with currently 40 signatory parties, including the European Union, is a unique actor that protects public health in developing quality standards throughout Europe (including all EU member states) in the field of medicines and their safe use, substances of Human Origin (SoHO), and cosmetics and food contact materials. EDQM activities are based on work sharing between member states and expertise, made available by member states in nominating experts to the working groups and on experimental work carried out by the experts and the national control authorities. Main activities include: a) the elaboration of legally binding quality standards for medicines and their components via the European Pharmacopoeia and the establishment of related reference standards, b) the standardisation of test methods for the quality control of biologicals, c) the coordination of the European network of Official Medicines Control Laboratories (OMCLs), d) the provision of policies/model approaches for the safe use of medicines, e) the establishment of programmes to combat/prevent falsification of medical products f) the establishment of standards for protecting consumer health in the field of cosmetics and food contact material together with the coordination of a network of Official Cosmetic Control Laboratories (OCCLs) and g) the elaboration of quality standards in the field of Substances of Human Origin (SoHO), together with programmes supporting their implementation in the field.

The CoE has been active in the field of blood transfusion since the 1950s and since 2007 activities in this field have been coordinated by the EDQM. The EDQM/CoE is responsible for the **Guide to the preparation, use and quality assurance of blood components**, including the **Good Practice Guidelines**, and maintaining the annual reports on collection, testing and use of blood and blood components in Europe.

With new scientific and technological developments emerging together with increasingly stringent regulatory requirements, and continuous efforts from BEs to develop and sustain efficient Quality Management Systems (QMS), the EDQM established, in 2010 and 2012 respectively, the **Blood Proficiency Testing Scheme (B-PTS)** and the **Blood Quality Management (B-QM) programme**. The B-QM Programme includes on-site assessment schemes such as training visits and audits, the development of guidelines, the organisation of training courses and conferences to support BEs in the implementation and improvement of their QMS.

Both these programmes were rolled out following discussions held between the EC and the EDQM, which highlighted the need for sustainable, on-the-ground activities to facilitate the implementation of the European Union (EU) Blood legislation and the EDQM/CoE standards. Both activities are thus co-financed by the EDQM and the EC.

For more information about the EDQM, please visit our website: https://www.edqm.eu/
For more information about our activities in the field of Blood transfusion, please visit the following relevant webpages:
https://www.edqm.eu/en/blood-transfusion-mission-65.html
https://www.edqm.eu/en/blood-transfusion-work-programme-69.html
https://www.edqm.eu/en/recommendations-and-resolutions