

## **GAPP Work Package 5 – Multi Country Workshop**

**Date:** 18<sup>th</sup> February 2020

**Time:** 10:00 – 13:00

**Venue:** CCAB (Centre de Conférence A. Borschette,  
Rue Froissart 36,  
1040 Bruxelles, Belgium)  
Room AB- 4D (4th floor)

### **Background:**

*Work Package (WP) 5 of the GAPP Joint Action (JA) will develop guidance on how a preparation process authorisation (PPA) system should or could be organised. The purpose of this Multi Country Workshop is to promote discussion to consider and gather information on the status of Preparation Process Authorisation (PPA) systems, the associated legislative requirements, guidance and procedures in place across MS CA's in the field of blood and blood components.*

### **Agenda:**

**10:00 – 10:15:** *Welcome address - Stefaan Van Der Spiegel (DG SANTE);*

**10:15 – 10:45:** *Overview of WP5 and Objectives of the Multi Country Workshop (WP 5 Leaders);*

**10:45 – 12:15:** *Multi Country Workshop;*

- a) Risk Assessment;*
- b) Application Process;*
- c) Framework for Competent Authority;*
- d) Review and Evaluation;*
- e) Authorisation;*

**12:15 – 12:45:** *Discussion, Questions and Answers;*

**12:45 – 13:00:** *Closing Remarks – Stefaan Van Der Spiegel (DG SANTE)*