**APEC Hanoi Recommendations on Implementation of Good Manufacturing Practices for Blood and Blood Products**

The APEC Blood Supply Chain 2020 Roadmap, welcomed by APEC Ministers and Leaders in 2015, calls on APEC Economies to implement Good Manufacturing Practices (GMP) throughout the blood supply chain to improve the availability of safe and quality blood and blood products. GMP can help ensure the use of efficient processes that lower safety risks while improving quality and availability. Currently, implementation and adherence to GMP standards for blood and blood products varies widely across the APEC region.

Achieving GMP is not an easy task – it requires an investment of time, human and financial resources, as well as adequate infrastructure and political support. But there are significant returns on investment in GMP. The integration of GMP standards promotes more efficient and safer processes, allowing economies to realize cost savings through regionalization or centralization, to decrease transmitted transfusion infections with advanced testing strategies, to collect quality plasma for fractionation, to implement important self-evaluations and to improve communication systems.

Domestic regulatory authorities play an important role in promulgating GMP-compliant blood management practices. The implementation of new and updated regulations provides prescriptive information regarding compliance with domestic blood policies / laws. By providing a domestic regulatory authority with authority to license blood establishments and take enforcement action (e.g. suspend a license) if the establishment does not comply with regulatory requirements, APEC Economies can have confidence in the safety and availability of their blood supply.

Without GMP, frequent recipients of blood and blood products, such as patients with primary immunodeficiencies, hematologic and bleeding disorders, are at a higher risk of exposure to blood-borne pathogens. Domestic blood systems following GMP standards deliver great benefits to those in need of life-saving blood and blood products therapy, such as clotting factors and immunoglobulins.

The recommendations for implementation of GMP for blood and blood products expressed here are intended to support APEC Economies' efforts to implement internationally-accepted GMP standards. APEC Economies should develop implementation plans to achieve these standards. GMP-compliant domestic blood systems lead to safe therapy for a healthy and productive economy.

**Recommendations:**

1. APEC Economies should recognize that implementation of GMP is essential to improving the quality, safety, and availability of blood and blood products.

2. APEC Economies should ensure that they have the four elements of a regulated blood system: a legal framework, quality standards, a competent domestic regulatory authority, and coordinated blood services.

3. APEC Economies should immediately start, or accelerate ongoing efforts, to implement GMP and should consider using the *WHO guidelines on good manufacturing practices for blood establishments* as an implementation standard in addition to referencing the WHO's guidance for *Quality Assurance and Safety: Blood Products and related Biologicals*. Use of common harmonized standards facilitates alignment of industry with requirements, enables collaboration among domestic regulatory authorities, avoids redundancies and delays for regulatory approvals, and allows faster access to blood and blood products.

4. APEC Economies should ensure that GMP compliance is enforced by a competent domestic regulatory authority mandated to regulate blood and blood products. The *WHO Guidelines on Management of Blood as an Essential Medicine* and *the WHO Assessment Criteria* can assist APEC Economies with establishing effective blood regulations and strategies for their implementation

    a. The domestic regulatory authority and the domestic blood system coordinating body should work together to develop a common understanding of GMP during the implementation phase with the appropriate expertise and training to conduct inspections of blood establishments and manufacturers of plasma-derived products. This training of inspectors should include emphasis on specific aspects of blood establishment technologies and the importance of GMP in this area.

5. APEC Economies should develop measurable indicators to monitor success and progress of GMP implementation.

6. APEC Economies should streamline work plans with other medicines regulation harmonization initiatives, including the APEC Life Sciences Innovation Forum's Regulatory Harmonization Steering Committee, in order to use limited resources in the most effective way.