This year marks the 20th anniversary of the European Medicines Agency (EMA). The EMA is an agency of the European Union (EU) located in London. The EU was established following World War II to bring together the individual countries of Europe under a legal structure to promote a “peaceful, united and prosperous Europe.” The EMA is one of the agencies that carry out technical, scientific or managerial tasks that help the EU institutions make and implement policies.

Specifically, the EMA is responsible for the scientific evaluation of applications for European marketing authorization for medicinal products submitted for approval under what is called a “centralized procedure.”

The centralized procedure is one way of seeking marketing authorization in Europe, and certain medicinal products (e.g., those that are biotechnologically derived and ones that are designated as orphan medicines) must follow the centralized procedure. The other ways to gain marketing authorization in Europe are “national” (one member state) and “mutual recognition”/“decentralized” (at least two member states).

Under the centralized procedure, companies submit one single marketing authorization to the EMA to allow marketing of the approved medicinal product throughout Europe.

The EMA was established in 1995. As the EU has grown in scope of authority and membership, the EMA has also grown in terms of its responsibilities. It now has a 20-year track record of ensuring the efficacy and safety of medicines for humans and animals across Europe, and promoting research and innovation. Today, seven EMA scientific committees and
The EMA now has a 20-year track record of ensuring the efficacy and safety of medicines for humans and animals across Europe, and promoting research and innovation. Today, seven EMA scientific committees and more than 30 working parties provide scientific expertise for the regulation of medicines by drawing on a pool of several thousand European scientific experts.

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The regulation of plasma protein therapies as medicinal products involves the workings of multiple committees and working parties. The primary committee for regulation of plasma protein therapies is the Committee for Medicinal Products for Human Use with the assistance of the Blood Products Working Party and the Biologics Working Party. Other committees play important roles. Some of these include the Committee for Orphan Medicines, the Pediatric Committee, and the Pharmacovigilance Risk Assessment Committee; all of which have been established more recently as the enactment of various EU laws expands the scope and responsibilities of the EMA. From an agency that started with the primary goal of facilitating a European-wide marketing authorization procedure, the EMA had evolved to addressing a life-cycle approach to regulating medicinal products.

The plasma protein therapies industry is global. It is important that regulatory bodies in different regions of the world not be isolated. In 2001, the EMA and the U.S. Food and Drug Administration agreed to work together in many critical areas. Both also participate in the International Conference on Harmonization. While legal and regulatory structures differ, and regional differences exist in epidemiology and risk assessment and perception, the collaboration of the regulatory agencies has proved to enhance understanding in a more global way.

The EMA has had an exciting path from 1995 to 2015. It has grown in size, authority, responsibilities, and expertise over these past 20 years. PPTA applauds the scientific expertise and openness of the EMA and wishes the EMA a most heartfelt congratulations for its impressive 20-year history.

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References