U.S. CHAMBER OF COMMERCE

April 2, 2020

Thierry Breton, European Commissioner for the Internal Market
Phil Hogan, European Commissioner for Trade
Stella Kyriakides, European Commissioner for Health and Food Safety

Dear Commissioners,

As the world confronts its most significant public health and economic crisis in modern times, Europe and the United States are uniquely positioned to lead a global response and grant patients and healthcare providers timely access to medical equipment and expedite research to find new treatments and vaccines. Similarly, we must consider long-term efforts to clear the way for global economic recovery on a sound footing.

The Commission and member states have moved swiftly to address many of the challenges arising from the pandemic. Unfortunately, businesses have encountered significant hurdles in moving critically needed goods and essential workers, both within the EU and between the EU and third countries. Following is a summary of key challenges and recommended solutions.

- **Export Restrictions.** Many policy tools other than export restrictions exist and may be more effective to address shortages and supply chain issues. In general, export restrictions should always be a last resort. When deemed absolutely necessary, export restrictions should be: transparent (i.e. they should be published or otherwise made publicly available); applied in a nondiscriminatory way; tailored to a legitimate objective (e.g., a shortage of a specific product should not be a pretext for restrictions on others); and temporary.

  At present, some companies have found that the new requirement for an authorization to export medical equipment and healthcare products outside of the Single Market amounts to a *de facto* export ban. Even when authorizations are ultimately granted, companies are reporting waits of at least 5-10 business days before they can ship goods. These restrictions make it difficult, if not impossible, for companies to produce much-needed medical equipment—including ventilators and respirators—which are manufactured in production

chains that span the Atlantic. Firms also face challenges moving medical equipment between member states and even between international locations of their own companies. We urge that the export authorization requirement—and any lingering export restrictions within the Single Market—be eliminated, and that the EU and member states refrain from imposing such restraints on healthcare products going forward. We also ask that general export authorizations be granted for all intra-company trade of components for medical equipment to ensure continuity of supply.

Our companies also have seen a proliferation of full export bans for medicines and vaccines and/or medical equipment at the member state level. Presumably, these measures were intended to prevent parallel exportation of products/equipment already released for sale on the local market, but not for finished or semi-finished goods or personal protective equipment (PPE) manufactured locally and intended for distribution or sale in other member states or third countries. Unfortunately, these export restrictions are preventing shipments from EU suppliers to non-EU manufacturing sites for production of medicines and medical equipment for global markets, including the EU itself. The European Commission and member states must continue to allow the movement of medicines, vaccines, and medical equipment (including PPE) from factories across Europe to where they are needed most.

- **Essential Service Providers.** Member states should adopt common definitions for "essential infrastructure," "essential services," and "essential workers" that are exempt from national and local quarantine or "shelter-in-place" orders. The U.S. approach is not perfect, but it has proven workable and provides greater uniformity across our federal system, and officials continue to work to improve the key reference, the U.S. Department of Homeland Security (DHS) Cybersecurity and Infrastructure Security Agency's (CISA) Guidance on the Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID-19 Response. Further, the EU and its member states should emphasize open, transparent, and ongoing industry consultation; ensure sub-central governments follow the same rules; provide frequent updates to this guidance based on ongoing input; and coordinate with international partners to avoid unnecessary and potentially damaging policy misalignments.

- **Movement of Medicines and Medical Equipment.** Logistics and transportation are essential sectors, and member states need to facilitate the movement of goods both into and out of the EU, and between and within

member states. While we recognize that member states are responsible for execution of the "Green Lane" guidelines, the Commission should continue to ensure their rapid implementation in order to facilitate efficient movement of goods across the EU's internal land borders.

Additionally, the Commission must press member states to adopt its guidelines on facilitating air cargo, including allowing cargo pilots to use passenger flights for repositioning. Common guidelines should also be adopted to ensure that non-symptomatic cargo drivers and pilots are not subject to quarantine restrictions at the member state level. Separately, the EU should urgently provide additional incentives for air cargo traffic to help make up for the significant reduction in passenger flights. This is particularly urgent, as 70% of medicine traded across the Atlantic is typically transported in the cargo holds of passenger planes. With a sharply decreased supply of cargo space, companies are facing price increases of up to 300-400% to ship their medicines and medical equipment.

Finally, while making sure that essential goods move freely, officials must recognize that delivery carriers cannot sort essential from nonessential goods without significant delay and cannot be profitable if permitted only to move essential goods, which would reduce the overall movement of cargo even further.

- **Medical Device Regulation**. We applaud the Commission's proposal to delay implementation of the EU Medical Device Regulation by one year and will encourage the European Council and Parliament to quickly agree to this proposal. Similarly, a delay on implementation should also be agreed for the In-Vitro Diagnostics Regulation.

- **Derogations to the EU Biocides Regulation.** As companies retool production chains to produce essential materials, including hand sanitizer, they require derogations from the EU Biocides Directive. These derogations are delivered by national competent authorities and only apply to the country in which they are issued. This makes it difficult to distribute hand sanitizer within the Single Market, including for companies' use for the protection of their employees. We encourage the Commission to have a centralized mechanism that would enable companies to get all the derogations needed in one administrative procedure.

- **Trade Barriers to Medicine and Medical Equipment**. The EU and the United States should pursue a coordinated approach to remove all tariffs on medical devices, personal protective equipment, pharmaceuticals, pharmaceutical ingredients, and other related products necessary to address the outbreak (e.g. sanitizer and disinfectant), and refrain from imposing new tariffs on these products in the future. Both should also champion global efforts to remove and prevent similar barriers elsewhere.

We appreciate your consideration of these matters and stand ready to provide additional information to enable quick action on these recommendations.

Sincerely,

Marjorie Chorlins
Senior Vice President for European Affairs

cc: H.E. Stavros Lambrinidis, Ambassador of the EU to the U.S.