



PART 3: COVID-19 PREPARING FUTURE SUPPLY OF PERSONAL PROTECTIVE EQUIPMENT (PPE)

Written by manufacturing and quality subject matter experts at Ansell for healthcare workers purchasing and wearing glove personal protective equipment.

LEARNING OBJECTIVES

1. Review government reactions and trade restrictions to increase in PPE demand
2. Consider supplier strategies implemented to minimize PPE supply risk throughout the pandemic
3. Explore required steps to prepare continued PPE supply through the second wave

GOVERNMENT REACTIONS TO INCREASED PPE DEMAND

To protect their supply and the growing impact of COVID-19, early in the pandemic France and Germany were amongst the first European countries who banned exports of hospital equipment. Whilst France banned export of healthcare FFP2 respirator masks only, Germany's list included healthcare and non-healthcare related PPE. To unite the countries and restore good spirits, the European Union (EU) executive arm, the European Commission, stepped in mid-March, removing the ban of export to other EU Member States. European Commission also introduced the Implementing Regulation, a requirement that all exports of PPE outside of the EU would be subject to an export authorization by Member States.¹ This was done to ensure essential supply of PPE in the EU. Their decision however had immediate PPE supply consequences to countries outside of the EU that relied on Member States feeding their supply chain.

A European Commission Guidance note² provided practical guidelines for the application of this new requirement. It included a margin of discretion and exports of certain quantities

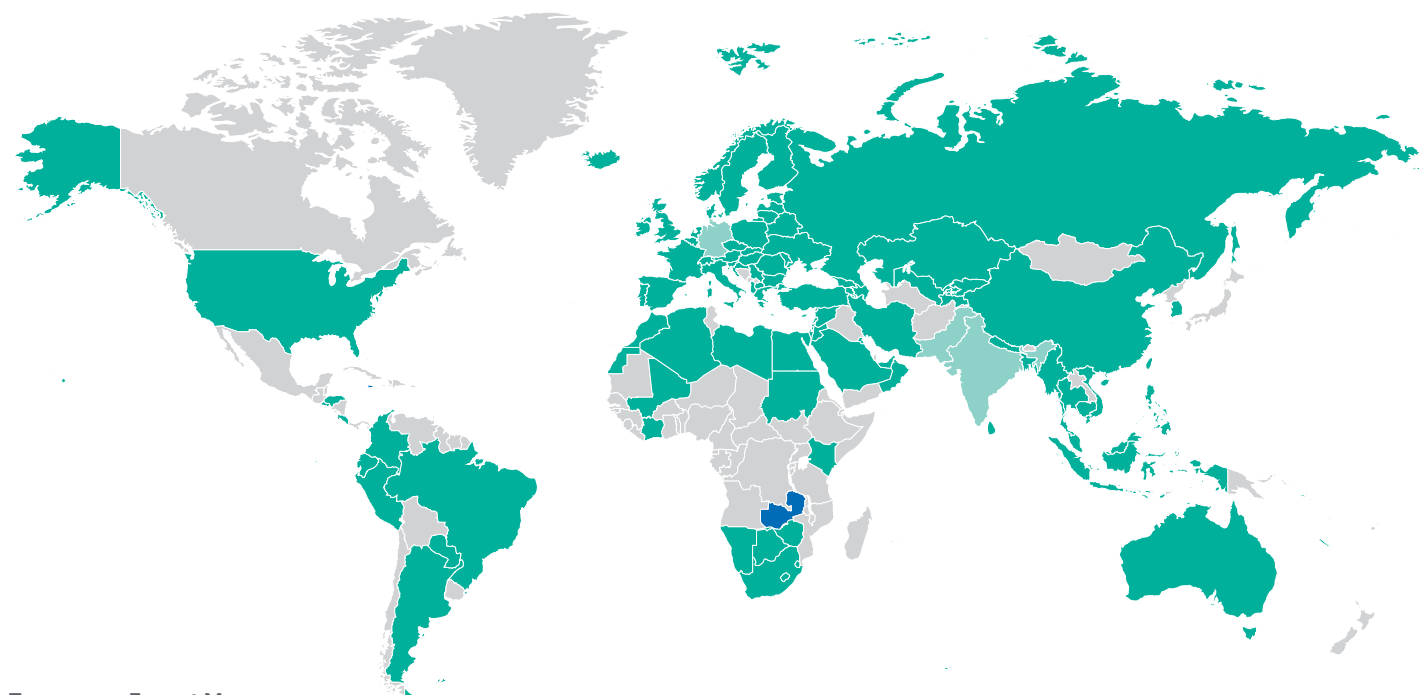
of specific PPE products may be authorized under detailed circumstances depending on the needs of Member States. This was done to ensure assistance was provided to developing countries and close allies, such as Switzerland and Norway. Notably Russia who also introduced their own temporary export ban, has been excluded even though the pandemic crisis is having a high impact on their healthcare system.

To protect local supply, following the European Commission regulation, both EU and non-EU countries, including Russia and Turkey began to restrict export of medical supplies.³ These included:

- FFP2 (N95) and FFP3 (N99) respirator masks;
- Protective goggles;
- Gloves (nitrile) with sleeve length of at least 300 mm;
- 12% hydrogen peroxide; and
- Nebulizers (nocospray).

COVID-19 Temporary Export Measures⁴

Affected products include PPE (e.g. masks, gloves), pharmaceutical products, hand sanitizer, food and certain other products



Temporary Export Measures

- Export restrictions/bans (95 countries)
- Export liberalizations (2 countries)
- Export restrictions and liberalizations (3 countries)
- None (139 countries)

Source: ITC Market Access Map (www.macmap.org) based on media reports and official legislations

Across the globe in the United States, the Federal Emergency Management Agency (FEMA) issued a rule to allocate scarce or threatened PPE for its own domestic use and banned exportation from the United States without explicit approval by FEMA.⁵ The rule covered five types of PPE:

1. N95 filtering facepiece respirators;
2. Other filtering facepiece respirators (e.g., those designated as N99, N100, R95, R99, R100, or P95, P99, P100);
3. Elastomeric, air-purifying respirators;
4. PPE surgical masks; and
5. PPE medical examination and surgical gloves.

This rule was structured to exempt Canada and Mexico, but as the pandemic progressed it began to have large impacts on local smaller countries such as Jamaica, Bermuda and the Dominican Republic. These countries rely on the US for more than 50% of their supplies of respirators and medical masks.

As a large provider of textile materials for masks and medical overalls, India's Directorate General of Foreign Trade banned export of these raw materials.⁶ This was to ensure supply for the local Indian market. Whilst China, who manufacturers over half the world's masks assured their own local demand needs was first met. Global organizations faced a similar challenge of manufacturing in China and supplying customers across the world

even though the Chinese Government claimed no new export regulation. However, as China reported infection rates under control they began making very public donations of PPE, and specifically masks to countries who had early outbreaks of cases such as Iran, Philippines, South Korea and Italy.⁷

Historically, most PPE manufacturing is performed within Asia due to lower labor costs and local access to raw materials such as natural rubber latex. Malaysia produces more than half the demand for medical gloves globally. Glove manufacturers quickly warned users of a global shortage of gloves as coronavirus-driven demand grew exponentially, the demand doubled with the government's partial lockdown of Malaysia. This led to the Malaysian Rubber Glove Manufacturers Association having to lobby the International Trade and Industry Ministry for essential PPE manufacturers to return to full capacity. This lobbying effort required support from many Western governments including Australia, EU, United States and the UK. The EU ambassador in Malaysia pushed for essential goods manufacturers and their supply chains involved in the production of vital medical equipment to resume operating at required capacity to meet the urgent global demand for PPE.

As case numbers increased over the first three months of the COVID-19 pandemic, governments acted rashly, looking out for their own countries best interests. However, as the pandemic progressed, governments began to make long term considerations and planning on a collaborative level.

STAYING AGILE WITH PRODUCTION AND COMMERCIALIZATION TO MINIMIZE THE RISKS

A manufacturer's perspective

Despite COVID-19 having its beginnings in late 2019, the global impact of the resulting pandemic from a supply perspective, was not fully appreciated until February 2020, with Chinese authorities declaring a workforce movement control which halted production in China. As the pandemic spread across the world, governments, many being main producers of key raw materials and finished PPE took similar actions, which severely impacted global supply. This, when combined with the unprecedented increase in demand and disruption of logistical transport that saw a sharp decrease in air transport, added pressure to the situation.

While there have been significant discussions from many countries advocating for the local production of PPE, this may not be feasible in the short term. Not only due to the time and cost of setting up manufacturing plants, but also the availability of secondary suppliers located in countries already experiencing significant production demands.

What strategies worked well during this period and, what are the lessons learned?

One of the strategies that has served well during this period was the availability of numerous warehouses located around the world to Ansell to enable quick access to local markets. However, for this strategy to be successful, and to be able to absorb severe peaks in demand, a significant amount of stock is needed to be kept at all times; which is costly, and therefore may not be practical all the time and for all products.

The second strategy, used in combination with the above, was to deploy manufacturing/production and sourcing diversification. This refers to an ability to manufacture PPE in multiple countries as well as the ability to manufacture the same product in various locations. Very importantly, sourcing diversification enabled us to have various source options for each key raw component of the product to be able to cope with disruption in other parts of the supply chain. While this ensures good manufacturing agility, there are ensuing difficulties in manufacturing a 100% identical product when using various suppliers and therefore, consumers need to be prepared to accept small differences in glove appearance and performance which continue to pass the uncompromising quality

standards while maintaining existing product claims. Protective solutions such as surgical gloves are classified as a medical device, and therefore are highly regulated, the above strategies cannot be achieved in the short term as they take considerable planning to ensure readiness.

Process automation is another strategy that has proven to be useful during these times where the response plan needed to consider manufacturing runs that use less people with social distancing measures in place.

Overall, there is not one single strategy but a combination of the above strategies that have helped to successfully mitigate some of the issues experienced during this pandemic. Along the way, even more lessons will be learnt, and greater improvements will be made to make sure, as an industry, we continue to protect supply in situations like the one we are currently experiencing.



PREPARING FOR A SECOND WAVE

In late April Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases in the US was already talking of the inevitability that the world will have a return of the virus and how we handle it will determine our fate.⁸ While South Korea, who are seen as one of the world's success stories, had their Korea Centers for Disease Control and Prevention Director Jung Eun-kyeong note the second wave had already hit Korea by late June.⁹

We are seeing countries, businesses and hospitals beginning to lift restrictions on elective surgery. In this process, some centers have begun to stockpile PPE in preparation of a potential second wave of the virus later this year. For some healthcare providers, this has heightened fear that a second wave of the virus will put more pressure on the supply chain with lack of certainty on PPE supply. Will Lange, chief of Honeywell's PPE business, believes the supply chain is not fully prepared for a second wave of massive demand for PPE and it will "probably take about nine months to get to a good spot."¹⁰

Unfortunately, the stockpiling is not necessarily supplied to frontline workers and the healthcare industry who need it the most. As governments and additional industries learn the importance of appropriate protection and the value of PPE, demand exceeds supply and prices will continue to be driven up. With a severe power imbalance between countries in accessing and purchasing PPE we are going to see developing countries struggle to protect their healthcare workers with recommended PPE.

Many feel COVID-19 has proven the importance of an open, rules-based global trading program that requires nations to roll back their trade barriers. In an open letter to the Australian British Chamber of Commerce several Trade Ministers said this outbreak should 'lead us to deepen our commitment to shared rules for the governance of global trade and investment'.¹¹ No country is entirely self-sufficient in the supply of all medicines, medical supplies and PPE, which shows why free-flowing trade plays a key role in crises such as this.

CONCLUSION

Recently WHO Director General, Tedros Adhanom Ghebreyesus spoke saying ***“No organization and no country can fight this pandemic alone. Only by working together will we overcome this global threat. The greatest threat we face now is not the virus itself, it’s the lack of global solidarity, and global leadership. We cannot defeat this pandemic with a divided world.”***¹²

Extensive reshoring of truly essential capabilities will minimize short term supply risks for local communities in business as economies stabilize. However, we shouldn’t allow those taking advantage of the crisis in undoing the decades of progress our global community has drawn together. We need to continue sharing the challenges and diversify our supply chains to make us all more resilient and protect us in the event of future shocks. To combat this global problem necessitates a global response. We all have a part to play. This isn’t the first pandemic and it won’t be the last, but will we be ready and what will we have learned to lessen the impact for next time?



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Please Note: Given the novelty of this coronavirus, recommendations from the source references are interim and advisory in nature and are based on current knowledge of the situation. Always ensure compliance with your local public health authorities regulations regarding the COVID-19 pandemic.

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