



The Compliance Vaccine Series: Building Immunity to Corruption COVID-19 Exposing Risks in the Medical Devices Supply Chain

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DUFF & PHELPS

DISCLAIMER



The contents of this webinar and document reflect thoughts of each of the participants and not their organizations.

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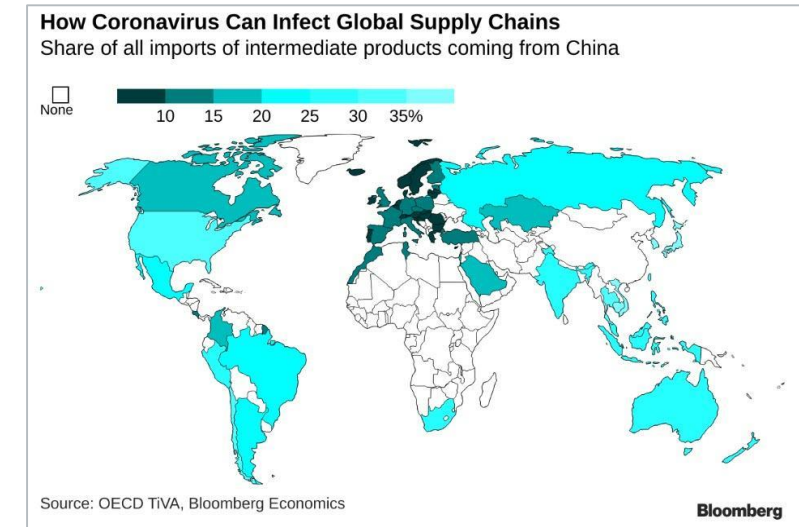
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Supply Chain Networks After COVID-19

COVID-19 will lead to significant change in global supply chains

- Bankruptcies and closures
- Changes in nature of current partners (downsizing, restructuring, M&A...)
- New ownership of existing partners
- Continued disruptions due to “second waves”
- Growing push to geographically diversify suppliers
- New pressures to “reshore” or “near shore”



Disruptions in Medical Device Supply Chains

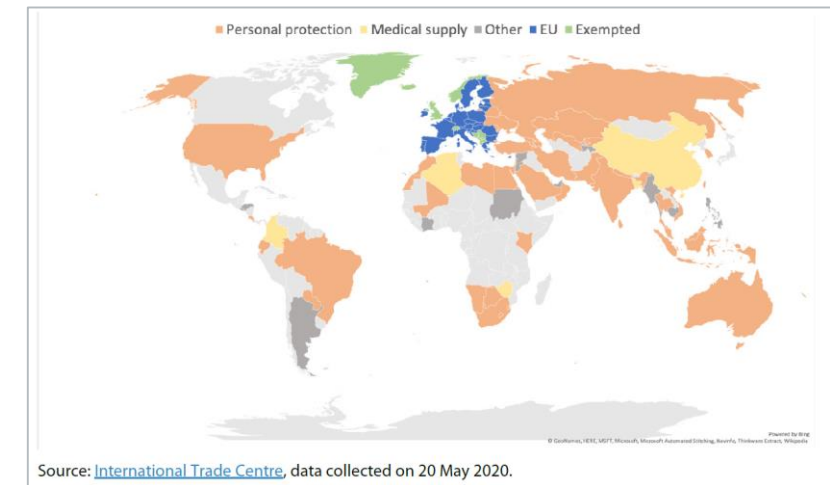
Medical device supply chains also face unique challenges

- Significant quality issues
- Spike in fraud and corruption
- Hyper-demand volatility
- Confusing regulatory environment
- Global state-imposed trade guidance
- Growing US-China geopolitical competition

“You now literally will have a company call you up and say, ‘Well, California just outbid you.’ It’s like being on eBay with 50 other states, bidding on a ventilator.”

- Gov. Mario Cuomo, NY State

Temporary PPE Export Restrictions





Fraud / Corruption in Medical Device Supply Chains

Medical device supply chains facing unprecedented fraud and corruption risks

- Result of significant gap between demand and supply, especially for PPE
 - WHO: global PPE production must grow by 40% to meet demand
- Government organizations, hospital systems and companies around the globe have fallen victim in recent months
 - Sellers, agents and manufacturers have all been variously involved

“You have buyers with no money and sellers with no product.”

*- Alexis Wong
HK-based trader
[Washington Post]*

As a result, governments are prioritizing actions against these crimes

- DOJ / FBI, DHS, ICE, FDA, USPS investigations and screening efforts
- European Anti-Fraud Office (OLAF) investigations



Impacts to the Medical Device Industry

- Continued upheaval up and down supply chain
- Growing concern of counterfeit parts
- “Whiplash” due to frequent regulatory changes
- Need to rapidly pivot to alternate component suppliers
- Uncertainty of new, often unknown and untested suppliers
- Rise of regional “consortiums” to pool purchasing power

“We’re all just fighting for ourselves making sure that we get ample supply, and it has been pure chaos to try and identify suppliers...many have asked for money down from 25% to 100% and you don’t know if you’re going to be getting counterfeit product or not.”

- COO of CentraCare Health System



NAVIGATING PPE PURCHASES

Dan Harris

IB

A photograph showing a person wearing blue nitrile gloves using a pipette to transfer liquid into a small vial. A microscope is visible in the background, and the scene is lit with a warm, golden light.

Finding Suppliers

- Import-Export Database
- Alibaba
- “Friend of a friend” referrals

A logo consisting of the letters 'I' and 'B' in a white, serif font, set against a dark red square background.

IB



Buyers

- Hospitals
- Governments
- Charities
- Entrepreneurs



01.

China's government does not like you.

No really, they don't.



02.

Your Chinese employees are not China law experts.

No really, they aren't.



03.

China Law: what's written may not be real life.



04.

And yet, the laws apply to foreigners. Hard.



05.

Oh, and they are constantly changing too.





Key Question: For what am I on the hook for?

- Understand export/import terms – ExWorks, FOB, CIF, DDP, etc.
- Quality issues
- Delivery dates



Applies to exporting following medical supplies:

1. Test Kits
2. Ventilator
3. Medical Protective Clothing
4. *Medical Protective Masks*
5. *Medical Surgical Masks*
6. *Disposable Medical Masks*
7. Infrared Thermometer

4, 5 and 6 = what's difference? What about face shields?

Product must have PRC Medical Device Product Registration Certificate and comply with quality standards of importing country.



What is medical use?



Beginning on April 10, China Customs started checking “medical supplies such as [cloth face masks]” for quality.

1. Medical Use Face Masks
2. Medical Use Protective Clothing
3. Infrared External Thermometers
4. Ventilators
5. Medical Use Surgical Caps
6. Medical Use Protective Goggles
7. Medical Use Gloves
8. Medical Use Shoe Covers
9. Patient Monitor
10. Medical Use Sanitary Wipes
11. Medical Use Disinfectant

This list is much broader than that in Order 5. Items 5 to 11 are not included in Order 5.





What is medical use?



A close-up photograph of a person wearing blue nitrile gloves using a pipette to transfer liquid into a small vial. The scene is set in a laboratory, with a microscope and other equipment visible in the background. A red semi-transparent banner is overlaid on the right side of the image.

April 25 Announcements

China's General Administration of Customs (GAC) and its State Administration of Market Regulation (SAMR) issued announcement on quality controls for non-medical face masks, Medical Masks, Medical Protective Suits, Infrared Thermometers, Medical Ventilators, and COVID-19 Test Kits. Medical use products on a permitted list may be exported non-medical masks on a prohibited list cannot be exported.





What is medical use?



If you want PPE orders to get through China customs, be certain of the following:

- The company manufacturing your PPE product is licensed to make **and** export that product.
- Your paperwork is perfect.
- Your PPE product is of good quality and not counterfeit.
- Your PPE can be legally sent to *and* received at its intended destination.



Why bother with a contract?



Clarity



Prevention



Enforcement





How we do it

It's all about the term sheets.





How we do it (2)

First in English.

Then Foreign
Language.





The Good Contract Guidelines

In writing

Liquidated damages

One language

Dispute resolution

SEALED



A close-up photograph of a person wearing blue nitrile gloves using a pipette to transfer liquid into a small vial. The scene is brightly lit, and the background is blurred.

Litigating outside China

Chinese courts are not obligated
to enforce most foreign country
court judgments...

and they don't.



- Thailand (no FM), Vietnam (no FM?), Malaysia (no FM), Korea (no FM), Taiwan
- Indonesia opens on June 30
- EU is open, but some countries are not. Germany. Spain. Poland.
- Turkey (no FM)
- Mexico
- United States



Be careful out there





Medical Device Supply Chains – Reacting to a Fluid Market

Suppliers pivoting to PPE/Medical Device Production

- » What did they do before?
- » Do they have a track record of producing at scale?
- » What is their reputation

Addressing risks for established companies

- » What is their reputation in the Medical Devices sector
- » What changes have they gone through as a result of COVID-19 – do new risks present themselves?
- » Time to reassess their risk profiles

Red Flags to look out for:

- How were they sourced / introduced?
- Unusual communication – WhatsApp, personal email addresses
- No history in the medical devices / PPE sector
- Does not have a demonstrable track record / corporate footprint / public profile
- Cannot explain the origin of the equipment or how their availability given current demand
- Unwilling to or cannot demonstrate that the supply chain is legitimate
- If an intermediary, lack of existing relationship with the seller
- Last minute changes to payment instructions or recipients

Looking Beyond China....What's being done to combat PPE fraud

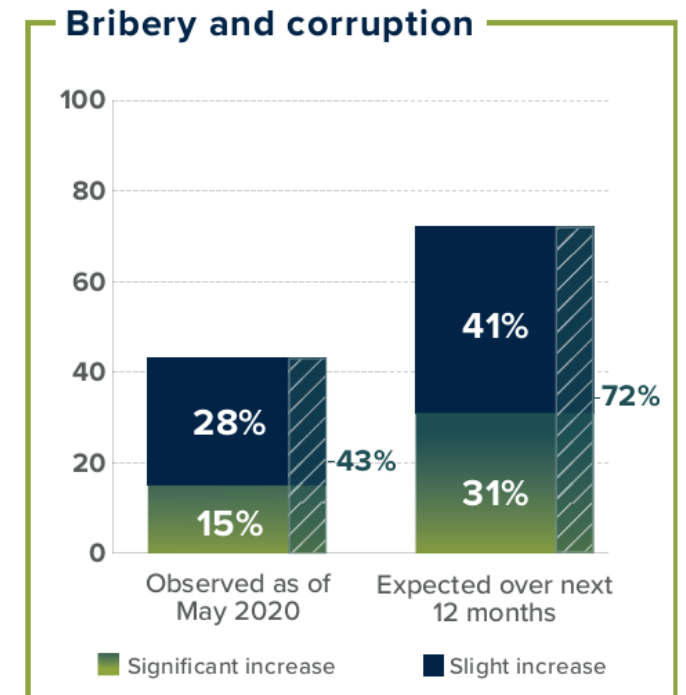
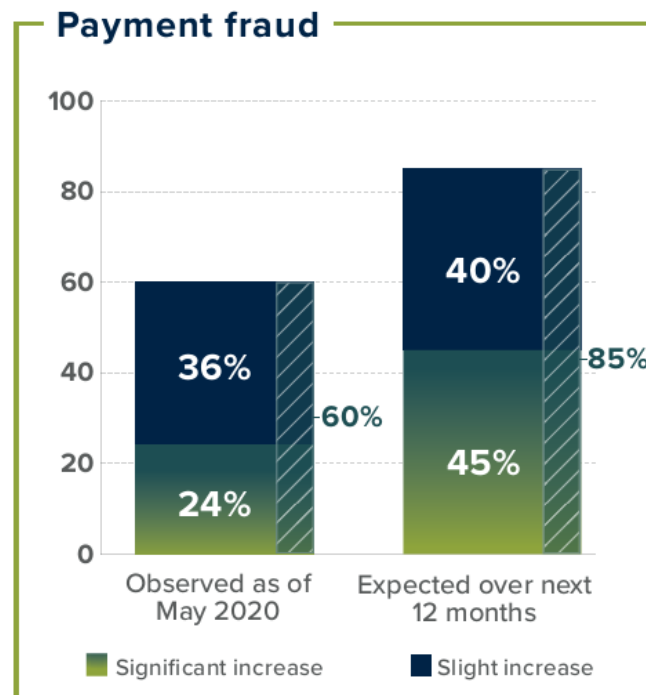
European Anti-Fraud Office (OLAF) has already identified over 340 companies acting as intermediaries or traders of counterfeit or substandard products linked to the COVID-19 pandemic.

The UK National Cyber Security Centre (NCSC) claims to have removed around 500 fake online shops selling fraudulent PPE.

The US authorities have initiated over 100 criminal investigations, and has prevented approximately \$1 billion in fraud.



Risks and Resilience



Source: ACFE – *Fraud in the wake of COVID-19: Benchmarking Report*

Questions



Please type your questions in the “questions” panel on the right hand side.



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Closing Remarks



Please join us for our third webinar in our “Compliance Vaccine: Building Immunity to Corruption” series at the end of July, looking deeper into PPE risk.