Asia Pacific Clinical Supplies Webinar Series

Friday 25 Feb 2022
0900 Singapore

GLOBAL™
CLINICAL SUPPLIES GROUP

ASIA-PACIFIC
WEBINAR SERIES

Agenda

- GCSG Introduction (Steve Jacobs)
- COVID Impact On Clinical Supply – from a logistics perspective (Mervin Sulistyo)
- China Importation Discussion (Tessa Lai)
- Closing remarks (Wendy Xia)

GCSG Introduction

Steve Jacobs
Chairman of the Board
GCSG, INC.

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Agenda

- The Global Clinical Supplies Group (GCSG)
  - *What we are*
  - *Who we are*
  - *Why we are*
- How to Get the Most Out of this Webinar Series
- Opportunities

GCSG – What We Are

- A volunteer, member-run, professional organization dedicated to clinical supplies
- 501 (c)(3) not-for-profit organization as defined by the IRS in the US
- We are the largest clinical supplies organization in the world
- 33 year old global organization

GCSG – Who We Are

- Professionals involved in all aspects of the clinical supply chain
- We are all ‘Stakeholders’ in GCSG
- We see ‘Vendors’ as ‘Partners’
- We come from all over the world

GCSG – Who We Are (Cont'd.)

Board of Directors:

- Steve Jacobs - GBS
  (Chairman of the Board)
- Joe Iacobucci, Moderna
- Karen McNamara, Infinity
- Dave Spillett, World Courier
- Becky Griffiths, PCI

Executive Director

- Christine Fattore, GCSG

Who Are We: Asia Pacific E-Team

Masako Ota
Clinical Supplies Management
Kyowa Kirin, Co., Ltd., Japan

Kristi Byrnes
Director, Quality Assurance
Nuvalent, Inc. Boston USA

Richard Rossi
Global Cold Chain &
Strategic Projects Director
CRYOPDP, Australia

Chan Liu
Comparator Strategist Lead,
Pfizer, Beijing, China

Puvi Bala
Client Services Director
Pilatus Clinical Services
England UK

Takuya Kitami
Country Director - Japan
4G Clinical Tokyo

Wendy Xia
Vice President, Head of Supply
Chain Agios Pharmaceuticals
Boston USA

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GCSG – Why We Are?

- Provide a forum for open discussion
- Share knowledge and industry best practices
- Educate new folks to our industry
- Provide solutions to problems
- Network, Network, Network

GCSG – Why We Are (Cont'd.)

Our Values

- Continuous Learning
- Professionalism
- Ethical Conduct and Transparency
- Integrity and Candor
- Courage and Risk-Taking
- Altruism in Service to Our Profession

How to Get the Most Out of This Webinar

- Ask questions, anytime!
- Exchange contact info, connect on Social Media (e.g. LinkedIn), then follow up after the conference
- Fill out the surveys – importance of feedback
- Share your experience with your boss and colleagues

How to Get the Most Out of This Conference (Cont'd.)

- Download presentations from website
- Keep relationships going – stay in touch
- Consider volunteering with the organization
- Enjoy yourself and **above all else** learn and network!
- We have our first live poll commencing now...

COVID Impact On Clinical Supply - a Logistics Perspective

Presented by Mervin Sulistyo

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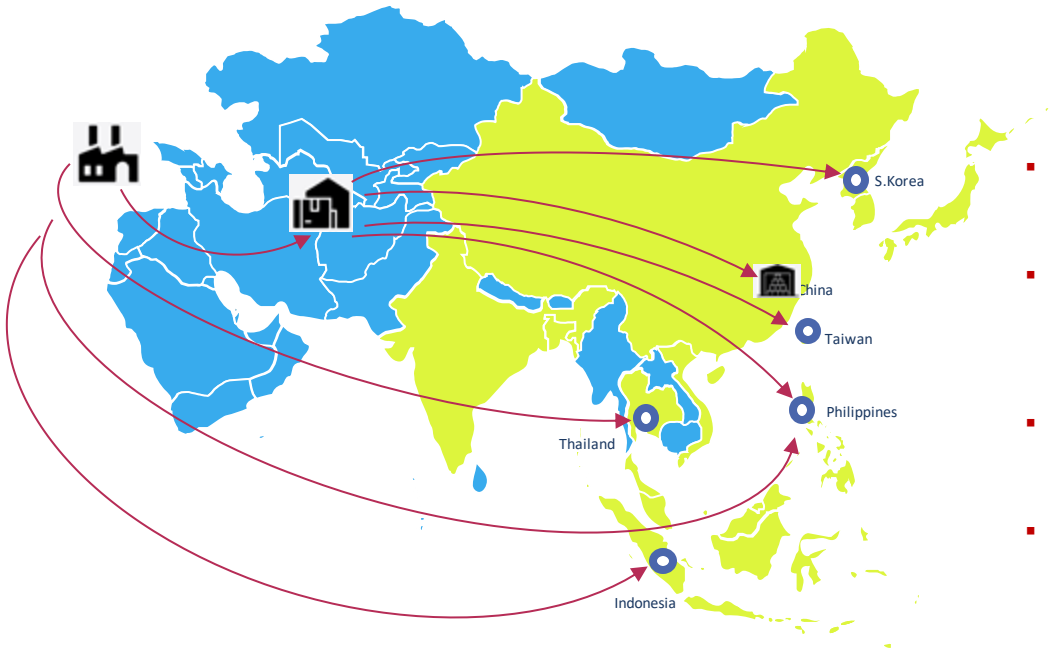
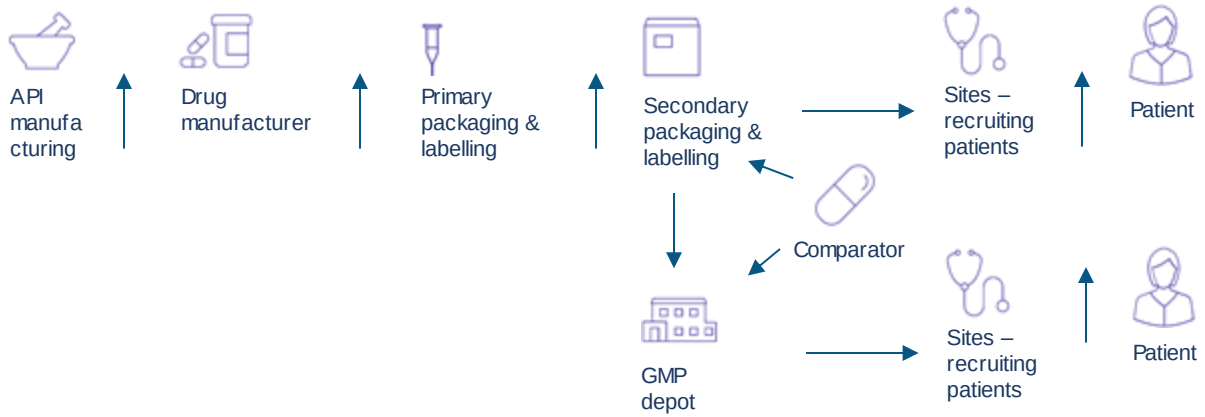
Case Study: Supply Chain Disruption



- An on-going Phase II Therapeutic Clinical Study in Asia Pacific
- High concentration of clinical sites across China and smaller sites across Asia Pacific with small patient pool
- IMPs manufactured in US and packaging vendor situated in US and EU
- Finished drugs are shipped directly to sites across Asia Pacific

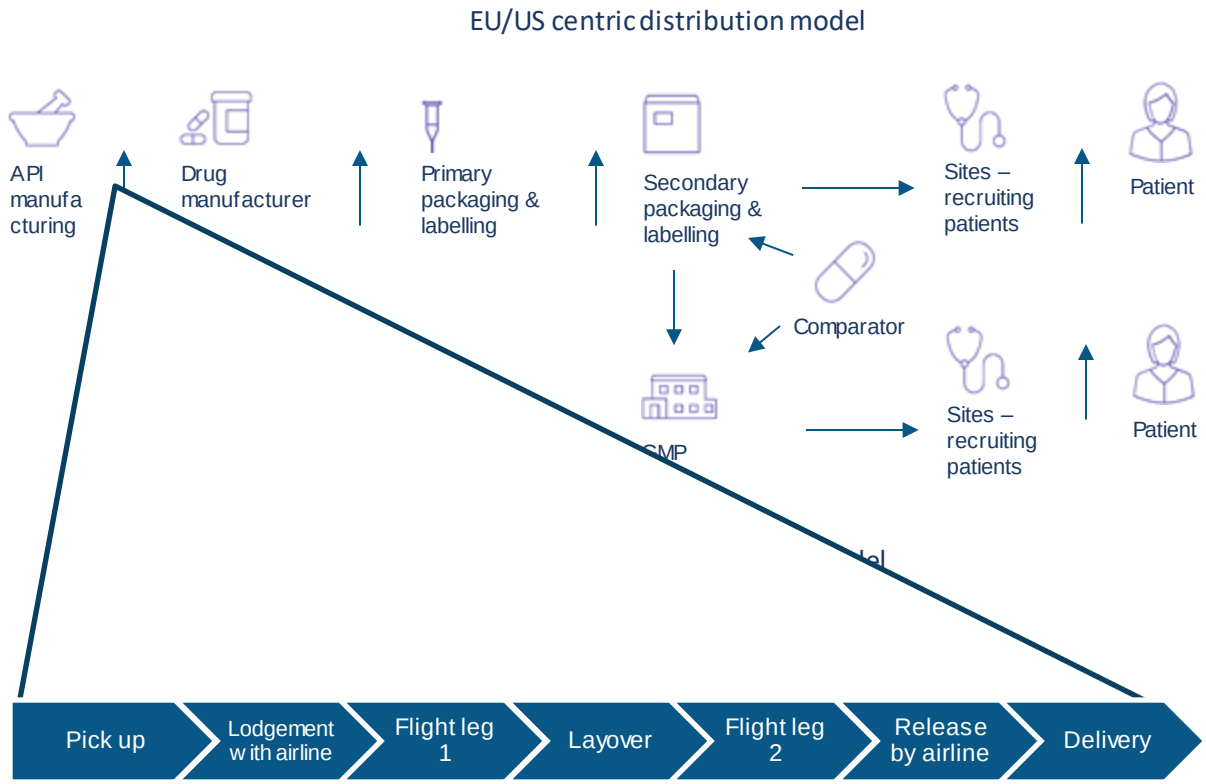
Classic Clinical Supply Model

EU/US centric distribution model

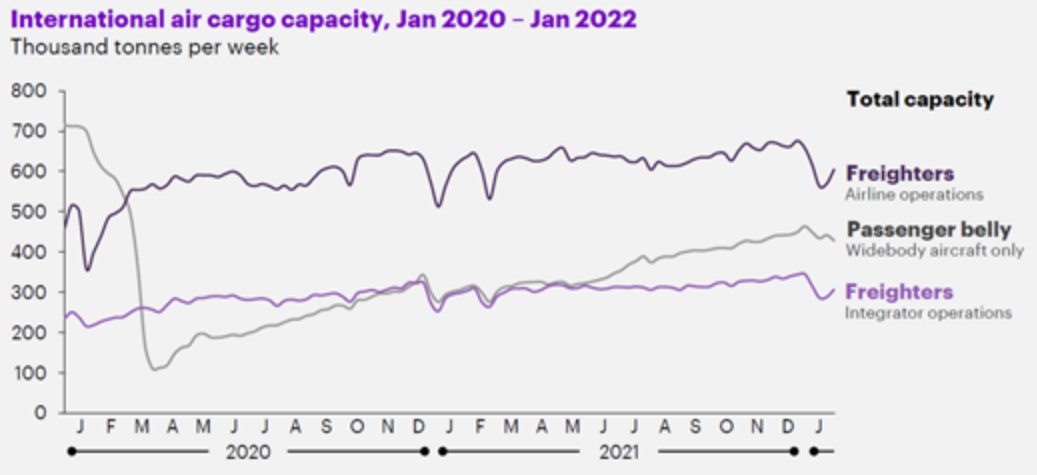


APAC centric distribution model

Classic Clinical Supply Model

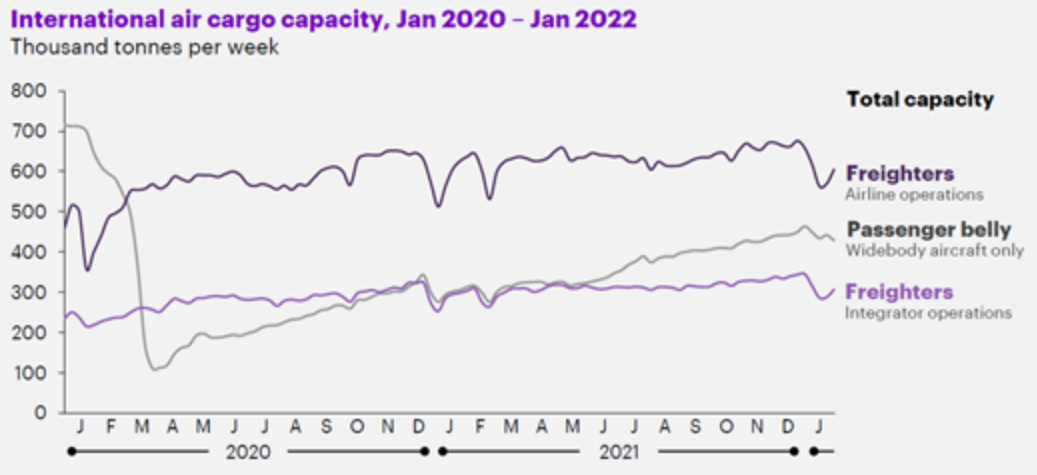


Airfreight Capacity - Latest



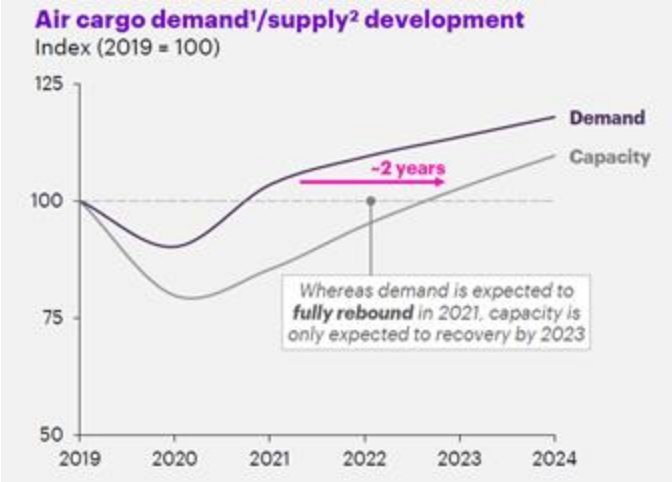
- Significant drop in capacity in 2020
- The drop is not uniform across all lanes
- A change in the make up of total capacity changes the new norm of airfreight

Airfreight Capacity - Latest



- Significant drop in capacity in 2020
- The drop is not uniform across all lanes
- A change in the make up of total capacity changes the new norm of airfreight

- Increase in demand is outpacing recovery of capacity
- Backlog of halted manufacturing during peak COVID, increase movement of COVID related products, and shift from seafreight
- As long as demand outstrip capacity, cost will remain high



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Forgotten Issue – Ground Handling

- Ground handlers manages the physical movement of freight within the terminal
- Reduced workforce capacity means extra time needed for loading and unloading of freight
- Highest risk of contracting COVID
- Any positive case leads to additional 24 hour delays in transit time

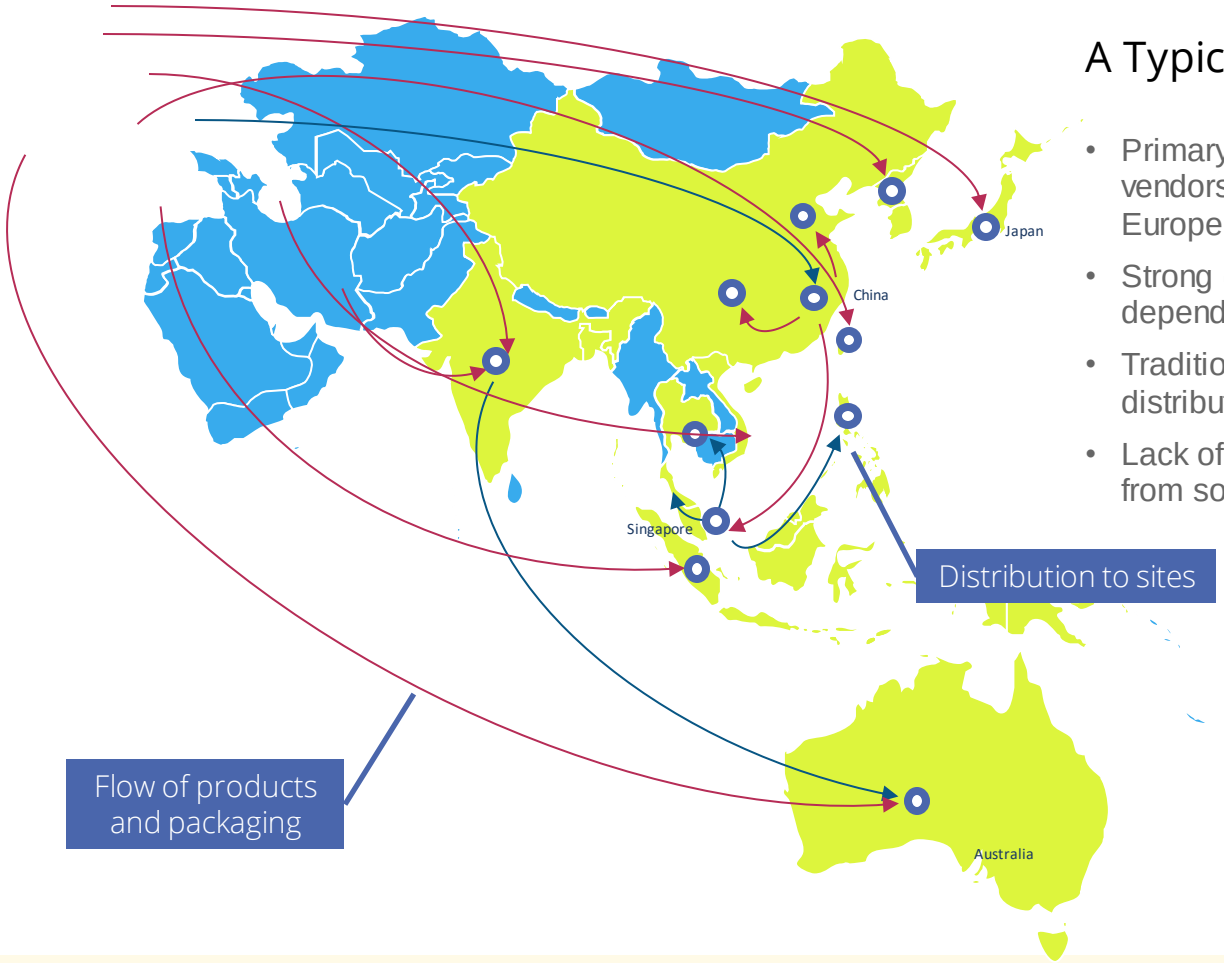
25%

Of ground handlers globally laid off since March 2020

COVID-19 Impact Within Value Chain

Areas Impacted	COVID Challenges	Implications Pre-existing model	Effect on Clinical Supply
Manufacturing	Reduced frequency and reach of flight	• Increase in door to door transit time • Temperature controlled packaging not qualified to new transit time • New packaging system requirement	• Increased risk of temperature deviation • New packaging unlikely to be as payload efficient • Increased demand on temperature controlled packaging • Increase packaging stock needed
GMP Depot	Cumulative delays from manufacturing logistics	• Added strain to centralized secondary packaging model • Two extra flight leg prone to delays	• Decentralised secondary packaging done at GMP depots • Logistic planning needed for packaging materials
Clinical Sites	Hospital sites likely to be COVID centres	• Delivery of medicines requires extensive training in SOP • any positive case will have domino effect on last mile distribution	• Increased demand for PPE, test etc (added cost) • Additional risk mitigation through agent onboarding

Classic Clinical Supply Storage Model



A Typically Siloed Supply Chain

- Primary manufacturer and packaging solution vendors are centrally located in US and Europe
- Strong global transportation network, highly dependable flight routes into Asia Pacific
- Traditional in-country shipment and direct distribution to sites, small pool of supply
- Lack of visibility on the supply chain journey from source to patient

Integrated Clinical Trial Supply Chain

Hybrid Supply Chain

- Diversifying and regionalizing supply chain and moving away from “single sourcing”
- Qualifying additional suppliers and vendors in Asia Pacific, reduce transit time to mitigate transport disruptions
- Focus on centralizing storage operations, utilizing regional hubs to overcome risks of flight restrictions and managing cost
- Using data to adequately forecast supply and demand, effectively reducing supply shortage in medical sites

Recommendation

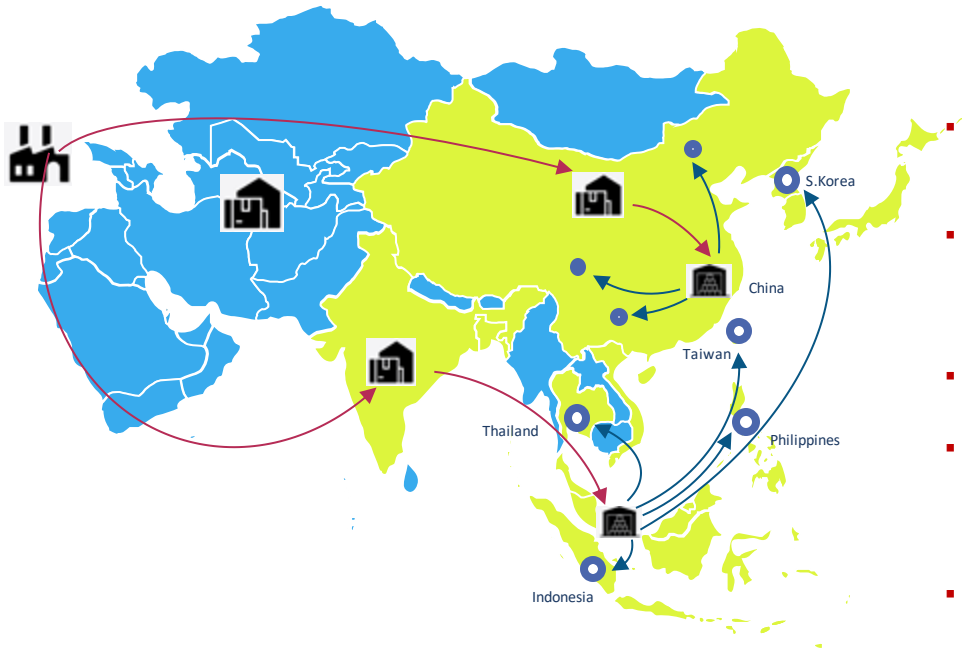
Implement risk mitigation strategy, involving quality

Build a nimble storage and distribution model

Take a holistic approach to supply chain review

Collaborate with your vendor partners

Case Study: Overcoming Challenges



- Moving away from “single-sourced” suppliers and into India and China, strengthening contingencies
- Building a regional hub in Beijing & Singapore
  - Each hub manage distribution pre-planning
- Qualification of ground transport as backup
- Deploying track and trace platform to monitor shipment from source to destination, better control on supply chain outcomes
- Dedicated Project Manager to proactively manage potential disruption

Thank you

Polling begins

China Importation Discussion 25Feb2022

Tessa Lai, Clinical Supply Asian Lead
Bristol Myers Squibb

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AGENDA

- Tariff code change for Placebo and blinded clinical trial kits
- Price Challenges for Clinical Supply
- Manage shelf-life expectation from import port City's FDA

2022 World Customs Organization Harmonized: System Updates: Placebos and blinded (or double blinded) clinical trial kits

From HS Explanatory Notes
3006.93 - Placebos and blinded (or double-blinded) clinical trial kits for a recognized clinical trial, put up in measured doses.

Market	Full HTS code	Comments
China	3006930000	
Japan	300693000	
Australia	3006930010	
Hong Kong	30069300	-
Korea	3006930000	
New Zealand	3006.93.01 00K	Of type made of sugar
	3006.93.03 00B	Of type made of starch or other foodstuff
	3006.93.05 00E	Of type in liquid form for oral intake
	3006.93.09 00L	Other

China Case Sharing

- BMS imported one batch double blinded products into China in Jan 2022.
- Product: Oral product, small molecule, package in bottles.
- Importation license: two ILs (One for active, one for blister) from Beijing FDA.
- Customs clearance application process:
  - Both active and placebo use the same code 3006930000
  - Two Customs clearance application sheet due on two ILs.
  - Customs questioned us to provide the CTA from NMPA and a memo to explain the study rational, then internal discussed for about one week.
  - Current status: Released.
  - Total clearance time: application submitted on Jan 19th, clearance released on Jan 27th.
- Further questions need to clarify:
- 1, Clarify with Beijing/Shanghai FDA, could we just apply one IL as the doubled kits are using the same tariff code?
- 2, If large molecule (3002) double blinded kits follow the same process, just apply IL, not CIQ anymore?

Price Challenges for Clinical Supply

- **Price challenges from Customs:**
  - Clinical product should be treated as commercial product even it didn't have a commercial value in clinical stage.

- **IP:**
  - No NDA submitted in China: Clinical value + PKG cost
  - NDA submitted in China: Transfer price confirmed by Finance with certain percentage discount.

- **Comparator:** PO price + PKG cost + margin

- I**nsurance cost and freight cost** should be included

Manage shelf-life expectation from import port City's FDA

- IL application requirement for shelf-life:
  - 12 months left when apply importation license;

- If we can't meet the shelf-life requirement:
  - Import port: Shanghai
  - Prepare additional documents to negotiate with Shanghai FDA:
    - Memo: explain the shelf life will be extended when more stability data or Sponsor will strictly control the dispensing and make sure patient safety.
    - Certificate Of Origin from Commerce bureau.

Thank you

Polling begins

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Closing Remarks

- Thank you for your attendance, comments and feedback!
- Next virtual event is tentatively scheduled for Friday 09 Sep 2022, 0900 Singapore
- We will continue host webinars such as today's and look for the best timing for a face-to-face conference

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