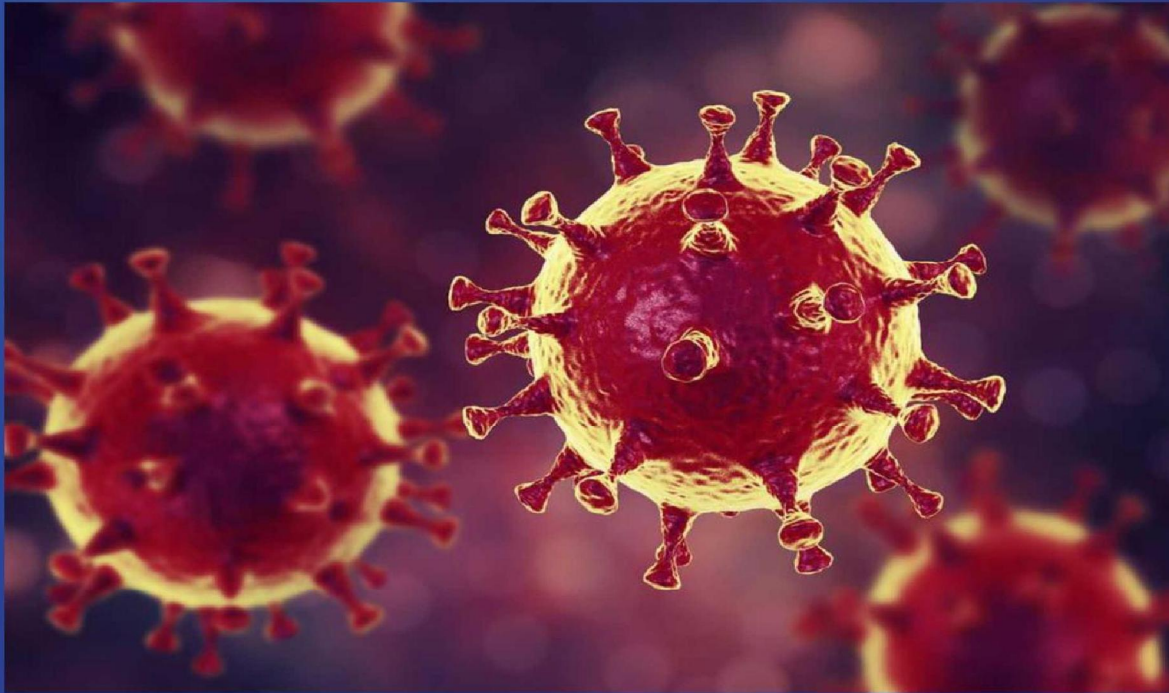


COVID VACCINE AND THE THREAT OF ILLICIT TRADE

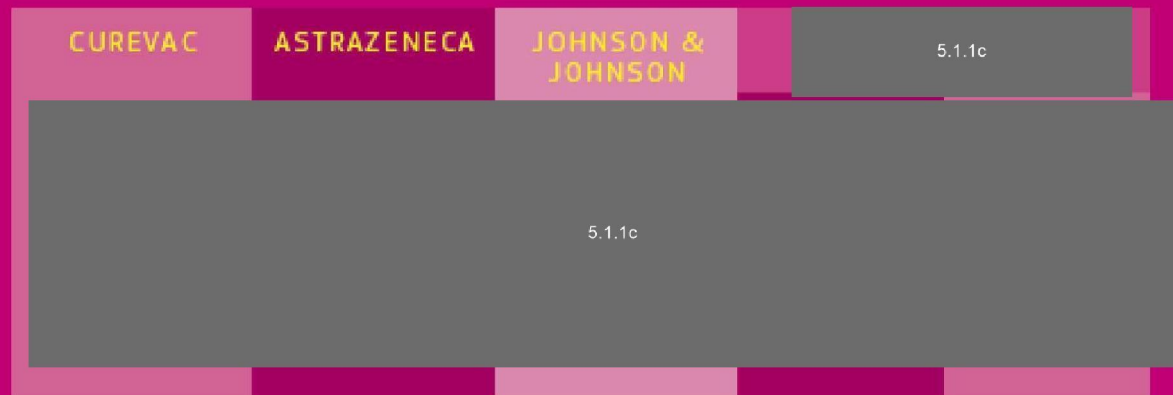


The EU vaccine supply chain

Advanced purchase agreements concluded on behalf of the Member States with 6 pharmaceutical companies

So far, the Commission has secured almost

2 billion doses



**if vaccine is only a one shot dose*

The EU vaccine supply chain

Updates:

- An agreement to purchase an additional 200 million doses of the COVID-19 vaccine produced by BioNTech and Pfizer, with the option to acquire another 100 million doses.
- A second vaccine, produced by Moderna, authorised on 6 January 2021.
- Other vaccines expected to be approved soon.

The EU vaccine supply chain

- ▶ **Most of the production, within the EU**
- ▶ **Orders and purchases by authorized national authorities only:**
 - Each EU Member State will receive doses based on a pro rata population distribution key
- ▶ **For imports:**
 - A CN Code for the SARS COV vaccine (3002 20 10) in force as from 1st January 2021. Help to smooth controls (both sanitary and customs)
 - Vaccines should be covered by a security and safety declaration and declared by using a standard customs declaration. Existing simplifications, will not be applied.

The EU vaccine supply chain

A closely monitored supply chain:

- Each EU Member State will receive doses based on a pro rata population distribution key
- National distribution hubs
- Shipping across each Member State under the supervision of National Health Agencies.
- Track and trace system to manage eventual product recalls.



The EU vaccine supply chain - threat assessment:

Risk of infiltration of the «official» supply chain by counterfeit/falsified products?

- **Relatively low risk:** secured supply chain by producers and regulators.



3 MAIN RISKS

- 1) Risk of theft
- 2) The logistics chain
- 3) On line sales/scams

1) RISK OF THEFTS

- Limited availability of and access to COVID-19 vaccines during the initial stages following licensing due to insufficient manufacturing capacity and unprecedented demand.
- Priority groups.
- High value products (a full lorry transport: more than € 100 million).



1) RISK OF THEFT

“The Lunapharm case” 2018:

- “Stolen medicines” originating from the Greek pharmacy *Ozbagdzi* (not authorised as wholesaler) and sold to a German parallel distributor.
- **Modus operandi:**
 - An OGC was illegally procuring the medicines from public hospitals via over-prescription and forged medical assessment reports.
 - Corrupted doctors.
 - Reintroduction of the stolen medicines into the legal supply chain through a long chain of European operators.
- **Key drivers:** different levels of price between countries.

2) THE LOGISTICS CHAIN

- **Cold chains:**

- Serious and malicious hacking attacks against some logistics companies.

- **Vaccination services** : need skilled workforce for the administration of vaccines and sufficient supply of personal protective equipment and medical (immunization) equipment.

- European market flooded with counterfeit and falsified COVID-19 products (test kits, hand sanitizer, masks, ventilators, or gloves)

2) THE LOGISTICS CHAIN

OLAF investigation on COVID-19 related products:

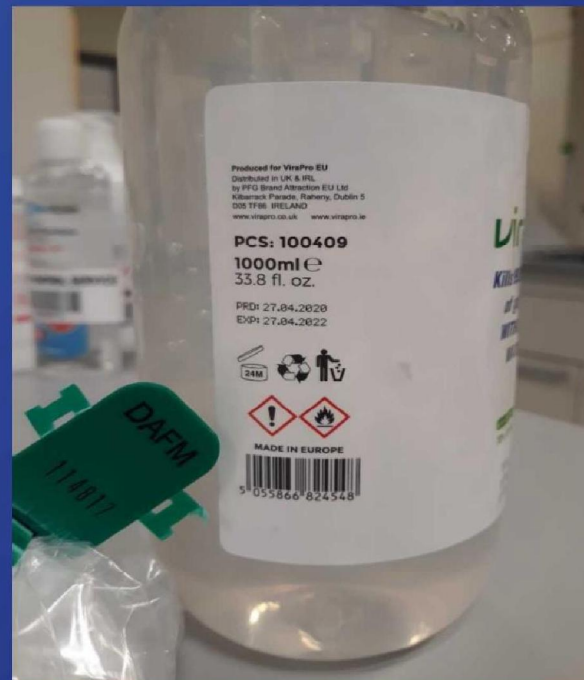
- Seizure of 14 million of substandard or fake medical products
 - Face masks
 - Hand sanitizers
 - Tests kits
- Identification of more than 900 suspicious operators trading fake or uncompliant goods.
- Joint customs operation on face masks



EUROPEAN COMMISSION

2) THE LOGISTICS CHAIN

Seizure of 150.000 liters of **dangerous hand-sanitizer** containing high levels of methanol



3) ON LINE SALES OF COUNTERFEIT VACCINES/SCAMS

- **Rogue online pharmacies, e-platforms, social networks:**
 - Main means of promotion of counterfeit medicines
 - Directly shipped to customers or via dealers
 - Lower the potential losses for counterfeiters (easy fitting in small parcel boxes or bubble wrap letter packets)
 - High ability to avoid detection
- **A challenge for customs and law enforcement agencies**
 - Lack of relevant information on postal/courier express shipments to allow risk-based controls by the customs and enforcement authorities.

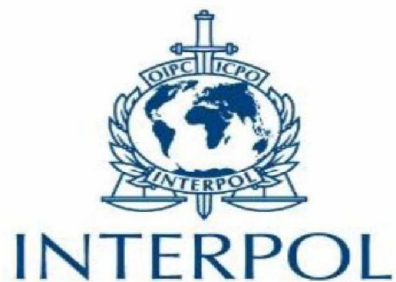
3) ONLINE SALES OF COUNTERFEIT VACCINES/SCAMS

- **During COVID-19 outbreak:**
 - Anti-malaria medicines
 - «Traditional» medicines that allegedly cure the disease
 - Scams
- **Key drivers of online medicines sales:**
 - Speed and convenience of purchases
 - Lower cost of products
 - Anonymous orders
 - No need to get a prescription
 - Allegedly powerful drugs forbidden for sales
 - Mismatch in supply and demand

CONCLUSION

1) Cooperation is key

- Exchange of intelligence in real time with law enforcement agencies
- Cooperation with right holders (role of the IP Enforcement Portal)
- Cooperation with the market surveillance authorities
- Cooperation with third countries (FDA, US Customs...)



CONCLUSION

2) Communication is key as well:

- Communicate on actual risks ...
- Without scaremongering and causing undue panic: an insufficient uptake could delay the containment of the pandemic
- **Clear and simple messages:** don't purchase vaccines on line; everyone will get vaccinated according to the priorities established by the national vaccination plans.

Many thanks for your attention

