SAFEGUARDING AGAINST FALSIFIED COVID-19 VACCINES

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Safeguarding against falsified COVID-19 vaccines

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> Introduction

The COVID-19 pandemic has created significant risk to life and health for the global population. Now that vaccines have been developed and are being delivered, a new threat with equivalent risks to patients has arisen: **falsified COVID-19 vaccines**. All the ingredients facilitating falsified vaccines have emerged in the midst of the efforts by State agencies, suppliers and healthcare practitioners to address the emergence of new mutations of the virus and efforts to treat patients and keep the populations safe.

Europe is no less vulnerable than any other region. Europe should be better prepared than most.

Safeguarding patients and health-care systems helps safeguard economies and our way of life. This means safeguarding against falsified vaccines entering the legal supply chains, into hospitals and vaccination centres, and from directly reaching the public through online sources. Everyone has a part to play in prevention activities, such as the strict control of the supply chain, and in good governance behaviours by those who have responsibilities for handling and processing vaccines for the public in not procuring the vaccines from outside the officially recognised sources. The optimum solution to safeguarding against falsified vaccines is to be able to ensure an end-to-end life cycle of the vaccine that provides assurance that theft, illegal diversion, misuse and recycling of waste does not arise. Corruption of officials, whether public or private sector, and activities by criminals have to be prevented to ensure that those who require the vaccines have a safe opportunity of receiving them.

> Circumstances that facilitate falsifications, thefts and grey markets

Less supply than demand in short to medium term.

Preventive measures

During the first phase of the roll-out of the vaccine supply, there is already a greater demand for supply to vulnerable populations (individuals) and front-line healthcare workers than the production and logistics system can provide. Added to this, some individuals in the non-priority category that want to be vaccinated will try to gain access to the vaccines. This in turn will necessitate an increase in the quantities of vaccines, where possible, and a strong public media campaign that the vaccine will be provided to all as soon as it is feasible. The media risk communication to the public should focus on awaiting the safe and effective vaccine from the public system to avoid the risk arising to them and their families from sourcing the vaccine from online illicit sources or the grey market.

New supply chains for COVID-19 vaccines.

Preventive measures

Pressures to distribute COVID-19 vaccines to hospitals and clinics for administration to the most needy has required developing adjustments to the normal pharmaceutical logistics system, which in turn risks weaknesses arising. The well-established and crises-tested pharma supply chain is capable of managing this challenge. Good governance procedures and processes for theft prevention and illegal diversion should be established and monitored at every level.

Procurement systems and suppliers from outside recognised pharmaceutical and vaccine logistical businesses.

Preventive measures

Crisis needs quick decisions. On the other hand, decisions under pressure increase governance risks and systems failure. Procurement officials with limited resources need to implement the decisions of others who need vaccines as quickly as possible. Procurement decisions and the outcome of delivery as a result require governance checks to ensure that what is ordered is what is delivered and that it has been administered to those who are prioritised for administration.

Exception for safety features, serialisation and ATDs.

Preventive measures

NO exceptions from FMD (Directive 2001/62 EU) for COVID-19 vaccines. For packages delivered to the EU, it is necessary to upload serial numbers to the EMVS system and to guarantee ATDs at least. Adherence to good documentary practices is necessary for tracking every vaccine to the intended consumer. This is not bureaucracy in a crisis. It is the guarantee of a system's effectiveness and safety for the intended patient.

Serialization - NO exception from FMD and Delegated Acts

Same vial format, stopper colour and crimp cap for the entire world and completely different appearance of vials of the same MAH, both will occur.

Preventive measures

Due to the high speed in development, necessity of fast production and initiation of the authorisation processes, the most appropriate and available vials fitting in the production lines are used. The result: all vials for the whole world produced by one MAH have the same appearance, only the labelling is different. On the other hand, order production will lead to different appearance of vials of the same MAH, even in the same country. This opens doors for uncontrollable illegal worldwide trade, relabelling and fraud. Manufacturers should add security measures on the stoppers, vials or caps that assist pre-informed health-care professionals in identifying falsified vials.

COVID-19 vaccines authorised in foreign countries are likely to be acquired for diversion to the illegal market in high demand and high-income countries, including European countries.

Preventive measures

Each single case of a foreign vaccine found on such markets has to be investigated and treated as a suspect illegal medicine distributed by suspect illegal market players.

Some countries with weak regulatory systems will not increase regulations for COVID-19 vaccine export or imports compared with those applicable for normal medicine export or imports.

Preventive measures

An import ban should be imposed on vaccines from suppliers or jurisdictions that have been identified as being involved in the supply of diverted vaccines. Improved monitoring of importations from unusual source countries may be necessary.

> Challenges along the supply chain

Manufacturing sites - what might happen?

Thefts at the production facilities, including thefts at contractor facilities.

Preventive measures

Manufacturers should have highly qualified quality and security personnel at the premises of all contractors who are **employed and funded by the authorisation holder** (client). SOPs (standard operating procedures) and regular staff sessions should cover all aspects of security and safety. As vaccines emerge as high-priced commodities for criminal focus, manufacturers will require the highest levels of security and intelligence to identify risks that may facilitate thefts of the COVID-19 vaccine.

Logisticians and wholesalers - what might happen?

Thefts at logisticians, first line/contract warehouses and during transportation.

Preventive measures

If no other strategy works, vaccines should be escorted and guarded during transport to the point of application.

All involved in the logistical chain should upgrade their security measures 24/7 to meet the risks associated with COVID-19 vaccines. All efforts should be made to eliminate risks of unauthorised access to transportation, storage facilities and sensitive data. SOPs have to be upgraded and should cover these expanded health and security risks.

Storage facilities, small wholesalers and import or export warehouses - what might happen?

In storage facilities, stolen and diverted vaccines will be replaced by falsified packages. As missing vaccines alert those expecting the shipment, it can be expected that the falsified vaccines, including packaging, will seek to mirror the genuine product.

Criminals will seek to reintroduce the stolen vaccines into the legal supply chain. Previous cases revealed that unauthorised wholesalers, acting illegally with falsified documents, were discovered to have committed these crimes.

To increase the volume of consignments and profits, criminals will enlarge deliveries of genuine products by mixing these originals with falsified packages. Small intermediary wholesalers are often used to conceal this.

Preventive measures

All packages have to be counted and verified at the time of delivery (entry) and at the time of distribution (output).These checks have to be done visually and technically by checking the package, the serial number (if applicable) and the anti-tempering device. All checks have to be documented. Any suspect product should be immediately reported to the national competent authority and to the marketing authorisation holder. If parallel traders are involved, they should be obliged to verify the supply chain back to the marketing authorisation holder in the source country, and they should be required to check the licences of all wholesalers involved.

Packages will be sold to parallel traders – when state controlled supply chain ends. Attempts to supply falsified vaccines into the wholesale trade will commence with the offer of supply with visual packaging images of the genuine product for approval, then the sample (sometimes genuine) packaging and followed by the falsified product.

Preventive measures

Never accept packages sent as representative examples for an entire shipment. The entire shipment should be rechecked if it is sourced from someone other than the originator. **Due diligence** should always be conducted on consignments received from new suppliers.

Unauthorised wholesalers and falsified wholesaler documentation will be used to introduce falsified COVID-19 vaccines to the market.

Preventive measures

Due diligence checks are mandatory. Compliance with due diligence checks should be strengthened by regulatory follow-up where risk-analyses reveal vulnerability to ensure this compliance.

Due Diligence:
Checking the language on the packaging and verifying safety features (serial number and anti-tempering device) are obligatory. Comparison and evaluation of expiry date with transport and storage time as well as comparing price with other offers from the same region should be in place. Wholesale dealer licences can be checked and compared with data in national or European databases, including data about the period of time the wholesaler exists.

Small intermediary wholesalers will be used to disguise and conceal the true source of products, and criminal activities that occurred elsewhere.

Preventive measures

Risk assessment of vulnerable wholesalers requires additional compliance inspections by the national competent authority.

Vast amounts of access vaccines, delivered to low-income countries, will appear on the market in high-income countries.

Preventive measures

Due diligence checks are mandatory. Each offer outside the state-controlled supply chain has to be investigated.

Every package that is illegally re-introduced in the legal supply chain, has been diverted or stolen before – or it is a complete falsification.

> Challenges and awareness at the place of application

Pharmacies, hospitals, medical clinics, physicians, vaccination centres - what might happen?

Diversion and theft of small to medium amounts of vials.

Preventive measures

Good governance systems adhered to in the receipt, administration and disposal of administered vials should be established. All documentation should accurately reflect reality. Training of staff, i.e. both vaccinators and support staff is essential.

Vandalizing, driven by different personal motivations.

Preventive measures

Well-trained and intensively screened staff only should carry out storage and handling of vials. SOPs at this level should also cover unexpected incidents.

Awareness by vaccinators and personnel preparing the vaccine for usage!

Discarded vials have led to several criminal cases in the past, where they were filled with other active ingredients or with non-active liquids in order to deliver them as genuine vaccines with falsified labelling and documentation.

Preventive measures

Each vial that does not originate from the marketing authorisation holder or its agent should be considered suspicious. It requires scrutiny to ascertain nothing is wrong. Package, leaflet, vial, vial-cap, stopper and content have to be examined and compared with genuine packages before dilution and injection. Each single deviation can pose a health risk (potential falsification) and the suspect vial should not be used. The national competent authority and the marketing authorisation holder should immediately be notified of any suspicion.

> Waste management

The transport and storage conditions of the COVID-19 vaccines are temperature sensitive, with few being storable at ambient temperatures. The risk of temperature failures and mismanagement will lead to vaccines being wasted, which have to be destroyed. Previous instances of criminality revealed that not all of these discarded packages reach the intended destruction facility for effective destruction. Finally, these vaccines or their packaging could end up back in the legal supply chain or the grey market.

In some cases, due to unexpected circumstances, some vaccines will expire. These vaccines and their packaging have to be destroyed in accordance with waste management legislation, and in a secure manner in order to prevent their re-entry to the legitimate supply chain or to illegal online supply lines. Criminals will be aware of the potential for profit from waste products. They will seek out weak links among those charged with the handling and disposal of waste connected to the COVID-19 vaccines. Finally, these packages could end up in the grey market or - with a new (false) expiry date - in the legal supply chain.

Preventive measures

Packages of COVID-19 vaccines are handled as sensitive and restricted goods. These special conditions also need to cover all packages that are dedicated for destruction. Waste-management needs to be very structured and secure. All packages, vials and other items dedicated for destruction need to reach the official destruction facility and be destroyed under effective monitoring. As the vaccination facilities are allocated all involved will require adequate training, not only in the patient documentation and administration of the vaccine, but also in waste-management regimes similar to those in secure distribution.

Employees and contractors working at vaccination sites in waste management are vulnerable to bribery by criminals who secure waste for illegal preparation and subsequent sale on the illegal market.

Preventive measures

Responsibility for secure and effective waste disposal does not stop at issuing a contract to a third party. Due diligence checks are required to be carried out on contractors and should ensure that contractors have also conducted due diligence on their staff and on sub-contractors.

The manufacturing companies themselves, or outsourced production facilities, can also be affected by criminal activities in the disposal of discarded equipment. Previous cases revealed that production machines for filling, labelling and crimping vials that were handed over to recycling companies were purchased by criminals. Such equipment could be used to produce counterfeit COVID-19 vaccines.

Preventive measures

Discarded and obsolete equipment should be effectively destroyed by reputable destruction facilities.

> Orders by unusual customers

Criminals, planning to falsify COVID-19 vaccines, will buy vials, stoppers and caps that have similar or identical characteristics to the authentic vaccine.

Preventive measures

Manufacturers of vials, stoppers and caps similar to those used in COVID-19 vaccines should be required to report any orders by customers who are not regular customers or who raise suspicions, to the national competent authorities or to law enforcement.

> Side-effects should attract attention

After administering COVID-19 vaccines, some people may experience adverse reactions. Vaccinators will be aware of expected reactions and will advise the patients. If substandard, for example for being out of the specified temperature controls for an inappropriate period at any stage, or if falsified vaccines have infiltrated the legal supply chain, patients may experience unusual or unexpected reactions. If the falsified vaccines contain no or insufficient active ingredient, there may be no vaccination reaction (swelling) by most of the patients at all.

Activities that should be started

Each unusual side effect that is not mentioned in the SPC (leaflet) has to be reported to the national competent authority, to EMA and WHO. If these side effects are associated with one single batch, these events could be caused by a quality defect of this special batch or by falsified products. Any unusual or unexpected reaction or the absence of an expected reaction should be immediately recorded and to the national competent authority notified.

If between 1 and 3 days, most of the patients vaccinated with the same batch develop unusual non-reactivity or unexpected reactions, evidence for investigations should be established very quickly.

Each of the vials and packages in question should be collected, and the trash bag marked. The trash bags should be kept in a secure place. Make visual analyses of the package, take photos and write a report on your findings. Collect all transport documents, temperature recordings and personal details of people who can confirm the findings. If the suspicion is very likely to be confirmed, the police and the local medicines or medical authorities should be informed.

> Cybercrime

Cyber-attacks on health-care facilities have increased in recent years in parallel with advancing internet connectivity. Everything from state-sponsored cyber espionage to organized crime are suspected of being involved in these activities. The Corona crisis has exacerbated these dangers.

The current need to implement and validate an effective cybersecurity system is of the utmost priority.

What might happen?

The supply chain, production facilities (including research institutions), transportation and distribution elements are extremely vulnerable to cyber-attacks. The cold chain as well as special storage equipment are notable weak areas for manipulation by hackers.

The use of computers at the vaccination sites is a vulnerable target to gain access to patient data and quantities of vaccines used.

Copy & Paste internet sites of supply chain partners created by criminals are used to access credentials. These credentials are later used to gain access to the supply chain.

The management of waste or discarded doses is another area prone to cyber-attacks.

Even internet-linked systems supportive to creating official documents (such as vaccination certificates) are in danger of being manipulated.

Activities that should be started

It is essential to implement and validate an **effective cybersecurity system** with established programmes and dedicated personnel to carry out cybersecurity activities.

Establishing **efficient training programs** that enable participants to recognize suspicious emails, phishing attempts and contact requests by previously unknown “colleagues” or strangers is essential. It must be clear to every employee that the weakest link will be the favoured target. To cope with this danger, the essential concepts are awareness and staff training by all the actors in the chain, including the clinicians in the communities.

All employees must follow monitored SOPs that cover social media use, passwords and securing online and offline materials.

Active monitoring of cybercrime activities, including looking for imitations of official sites and possible use of leaked credentials on illegal “paste” sites, is necessary.

Each suspicion needs to be documented and investigated.

> Warnings to the public via social and printed media

What might happen?

Private sales of COVID-19 vaccines by people who have access to unused doses.

Key-Messages to the public

Vaccine distribution is in the state's authorised supply chain. There is **NO legitimate private market** for COVID-19 vaccines.

There will be offers of COVID-19 vaccines via unauthorised outlets, such as on e-commerce platforms, social media and internet websites.

Key-Messages to the public

There are NO legitimate offers of COVID-19 vaccines on the internet or elsewhere. All these offers are either diverted, stolen or falsified. They may even be fraudulent offers without any intention of supply. **If you buy these products, you might commit a crime.**

There will be offers of "generic" COVID-19 vaccines via unauthorised sources, such as internet web sites and through other outlets.

Key-Messages to the public

There are NO legitimate generic COVID-19 vaccines at this time.

There will be offers of COVID-19 vaccines that claim to be authorised somewhere else.

Key-Messages to the public

Only COVID-19 vaccines authorised in your country are legal and controlled by your national medicines control laboratory. To avoid any possibility of receiving falsified vaccines, **do not procure from outside the legal supply system**.

There will be offers of COVID-19 vaccines that are still in clinical trials testing and not authorised yet.

Key-Messages to the public

Vaccines still in the clinical trial phase have **no proven safety or efficacy**. Only vaccines that have received authorisation from medicines agencies can legitimately be procured and supplied for immunisation.

Offers of COVID-19 vaccines at a very low price.

Key-Messages to the public

Vaccine distribution is state-controlled. There is no private market for COVID-19 vaccines. Cheap offers always have a catch.

Offers of COVID-19 vaccines at high prices to companies that are assumed to want their employees vaccinated.

Key-Messages to the public

Vaccine distribution is state-controlled. **There is no private market for COVID-19 vaccines. These vaccines have either been diverted or stolen.**

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Hannes H. Würkner, an official veterinarian, was as active inspector founder (2004) and until 2020 coordinator of all medicines enforcement activities at the national competent authority for medicines of Austria. During his service, H.H. Würkner established an inter-ministerial working group, bringing together police, customs, justice and laboratories, which led to a close successful mixed team – The Austrian Medicines Enforcement Group in 2005.
At the European level, H.H. Würkner was a member of HMA WGEO (Head of Medicines Agencies Working Group of Enforcement Officers). Twice he was elected to the management committee, the second term as vice-chair. In addition, he served as head of the Training & Education Work Stream within WGEO for three years, until 2020.
H.H. Würkner enjoys sharing his experience and knowledge with university students, pharmaceutical industry employees and high-ranking decision-makers.
On special occasions, the Ministry of Health delegated H.H. Würkner as state representative to the Council of Europe and WHO.

K. Gronwald has long-standing experience (24 years) in fighting pharmaceutical crime in a national and international context at the Federal Crime Police Office (BKA), Germany. He is a founding member and was a continuous participant of HMA WGEO. In 1998, K. Gronwald was a founding member and since then continuous participant of the PFIPC (Permanent Forum on International Pharmaceutical Crime) and was PFIPC Secretary from 2011 to 2015. K. Gronwald also supported various projects at CoE and WHO.
K. Gronwald is Co-founder and since 2019 Senior Consultant at KCC Consultants, Germany.
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Mickey Arieli, a pharmacist, is a founder and former director of the National Division of Enforcement of the Israeli Ministry of Health.
Arieli has worked with Israel National Police and other international enforcement units in cases regarding violations of Public Health. He was also involved in a project with the Prime Minister's Office regarding the connection between organized crime, terrorism, and pharmaceutical crime.
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PreventFakeMEDs.org

is a non-profit and non-governmental organisation (Austrian-ZVR: 1124064453)
focusing on the prevention of falsified medicines in Europe.

Almost all decisions in the pharmaceutical sector that have financial implications
or consequences for the availability of medicines, promote or reduce the risk
of illegal or even falsified medicines entering the market.

PreventFakeMEDs.org aims to reveal these interrelationships and thus create
an awareness among all actors in power so that this risk to public health is taken
into account at every single step.

PreventFakeMEDs.org