

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

ADVICE

ON THE APPLICATION OF THE MEDICRIME CONVENTION IN THE CONTEXT OF **COUNTERFEIT COVID-19 VACCINES**

MEDICRIME COMMITTEE

STRASBOURG, 27 APRIL 2021



Background

The Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (the MEDICRIME Convention), is an important legal instrument to be implemented by Parties, member States of the Council of Europe and other countries to prevent and combat the presence of counterfeit (hereinafter falsified) vaccines, that is vaccines with a false representation with regard to their identity and/or source, as well as the diversion of legally produced vaccines from the legal supply chain. As more vaccines have become authorised by regulators around the globe for use, there have been increasing reports of seizures of falsified vaccines.

Key messages

States should recall that:

- 1** Every COVID-19 vaccine **removed illegally** from the legal supply chain is outside the necessary regulatory control systems that guarantees vaccine integrity and prevents the intended patients from receiving it.
- 2** Every COVID-19 vaccine **removed from and illegally reintroduced into the legal supply chain risks** being substandard and will be done for an illicit gain and not for patient welfare.
- 3** Every COVID-19 vaccine **illegally reintroduced into the legal supply chain having previously been removed** from it risks being commingled with falsified vaccines which will be difficult to detect.
- 4** Every COVID-19 vaccine that is **falsified** is a risk both to vulnerable persons and to healthy persons.
- 5** Every COVID-19 vaccine made **available directly to the public** through **online sources**, including social media, e-commerce platforms and on the web, is outside the legal supply chain and lacks the clinical care that is required for the vaccination of patients.
- 6** Every COVID-19 vaccine **supplied from outside the legal supply chain**, whether stolen, illegally diverted, or unlicensed/unregistered/unauthorised, risks being a falsified vaccine.

States should proactively take preventive actions by:

- 7 Working with **industry and trade** to strengthen the supply chain to prevent thefts and illegal diversion of authentic COVID-19 vaccines from their intended markets and health service providers.
- 8 Working with **health service providers and healthcare professionals** to ensure the authenticity of COVID-19 vaccine supplies they receive and their administration only to those intended to receive them.
- 9 Working with the **relevant industries, health service providers and healthcare practitioners** to strengthen the disposal systems for COVID-19 vaccine waste products to prevent diversion to the illegal chain and their subsequent reintroduction and re-use as falsified vaccines.

States should take proactive action to:

- 10 Train the **relevant public officials**, in particular customs authorities involved in border surveillance and law enforcement, on profiling and detecting falsified COVID-19 vaccines, including by strengthening their ability to identify falsified documentation, labelling and packaging.
- 11 Conduct **awareness training for the criminal justice sector** on the purpose and intent of the MEDICRIME Convention. In particular, there needs to be an awareness of the direct and indirect impacts and threats created to individuals and the public health system by falsified vaccines. This includes the impact on the pandemic control measures caused by falsified, stolen and illegally diverted COVID-19 vaccines. It is crucial for the criminal justice sector to be aware of what this type of crime means.
- 12 Conduct **public awareness campaigns** on the risks of procuring COVID-19 vaccines from sources outside the public health system, such as a result of online promotions, and on how to identify falsified labelling and packaging.
- 13 Monitor **suspicious transactions** with regard to the instruments and devices that are needed to produce and market falsified vaccines, including syringes, vials, caps and crimping tools, printmaking equipment and tools (for COVID-19 labelling and certificates), etc.

APPENDIX

In 2020, the Committee of the Parties of the MEDICRIME Convention advised Parties, member States of the Council of Europe and other countries on how the Convention could assist in addressing the extraordinary challenges that the COVID-19 pandemic had created for the authorities in such countries (1).

Now that vaccines have been successfully developed to prevent the disease, it is necessary to focus on addressing the emerging challenge facing countries: the production and supply of falsified COVID-19 vaccines (2).

Explanatory Report

1. The purpose of the Convention is to protect public health through criminal law and the criminalisation of certain offences. The removal of the vaccines from the legal supply chain (including from hospitals, medical clinics and distributors) for diversion to unauthorised supply means that the legally required regulatory control systems, including temperature-control requirements, is ignored and impacts on vaccine integrity (Article 6, 7, 8 and 11). It also results in preventing patients in the legal supply chain from receiving the vaccine as intended by the public health system.

2. Reintroducing vaccines into the legal supply chain without strict regulatory controls avoids the verification of their safety, efficacy and quality that are intended to prevent falsified and substandard vaccines from reaching patients (Articles 6, 8 and 11). This affects patient safety as well as the public health system and may occur not only in countries with weak regulatory systems. Criminal actions only have regard for the perpetrators' own gain to the detriment of everyone else. The Convention requires that such actions to intentionally breach the legal supply chain are criminal offences under national law (Articles 8 and 9).

(1) Council of Europe, MEDICRIME Committee, *Advice on the application of the MEDICRIME Convention in the context of COVID-19*, Strasbourg, 8 April 2020. See: <https://www.coe.int/en/web/medicrime/covid-19>

(2) UNODC, *COVID-19-related Trafficking of Medical Products as a Threat to Public Health*. Vienna, 2020. See: [UNODC Research](#); INTERPOL, *INTERPOL warns of organized crime threat to COVID-19 vaccines*, 2 December 2020. See: [Global alert](#); EUROPOL, *EUROPOL predictions correct for fake COVID-19 vaccines*, 4 December 2020. [Press release](#); WÜRKNER, H.H., ARIELI, M., GRONWALD, K., et al., (2021): *Safeguarding against falsified COVID-19 vaccines*, PreventFakeMEDs.org, February 2021.

3. The reintroduction of diverted vaccines risks being accompanied and comingled with falsified vaccines, allowing the falsified versions to hide in plain sight. This makes it almost impossible for authorities to detect them. Even by checking the product packaging, the falsified ones may not be scrutinised and may create the impression that all the vaccines are the same and genuine. The Convention recognises that COVID-19 vaccines that are outside the legal supply chain cannot be introduced into the legal supply chain unless they are authorised as regards their safety, efficacy, and quality by national/regional regulatory authorities. They cannot legally be procured, stored, supplied or administered to patients (Article 5, 6, and 8). Falsified documentation is needed to infiltrate the legal supply chain (Article 7).

4. Healthy persons may be at risk of getting infected by those vaccinated with falsified vaccines. Persons vaccinated with falsified vaccines are likely to take fewer precautions against the risk of exposing themselves to infection, believing that they are now protected (Article 19).

5. Healthcare professionals receive specific training on the vaccination of COVID-19 vaccines and must follow protocols to ensure patient safety in being vaccinated and following vaccination. This professional healthcare cannot be provided via email.

6. When vaccines are outside the regulatory controlled system, their safety, efficacy and quality cannot be guaranteed. They are considered to be falsified and substandard vaccines. Only authorised/licensed COVID-19 vaccines should be administered to patients and only to those for whom public health authorities have determined their administration. Public health authorities determine the priority for this administration. Any deviation will be an unauthorized leakage from the vaccine chain.

7. Increased communication with industry is required to ensure the prevention of thefts, leakage and otherwise illegal diversion of COVID-19 vaccines through the life cycle of the vaccine. Until a production capacity is reached that satisfies global demand, there is a risk that the vaccines will be illegally moved from people in need to those who do not wish to wait their turn for vaccination.

8. Health service providers and healthcare professionals are also vulnerable to pressure to divert vaccines from their intended patients. When this happens, it is also likely that criminals will exploit bad, unethical, and illegal practices to make a gain for themselves at the expense of patients and public health.

9. The life cycle of the vaccines needs to be considered in preventing them from falling into the hands of criminal groups. This includes those responsible for waste disposal, whether they be cleaning staff, logistics providers which move and store waste, or staff working on waste disposal plants. This requires a robust and effective governance strategy to ensure that waste, whether it be empty or partially empty vials, packaging or used syringes, be insulated from leakage to criminal groups for the manufacture and supply of falsified COVID-19 vaccines.

10. Everyone with responsibilities for the prevention, detection and responding to falsified COVID-19 vaccines should be trained in their role. States should use all available expertise within their control and use industry experts where both needed and available (Article 18).

11. A greater awareness is required, in particular by those in the criminal justice sector, of the value and support that the MEDICRIME Convention offers to the ratifying States. The Convention makes clear how the investigation and prosecution of the offences that it covers require the expert support of public health authorities, and the true impact of these crimes have on victims. Such crimes and their impact cannot be simply regarded as administrative and regulatory issues but are criminal in nature and impact. (Article 17).

12. The public needs to be aware of the risks associated with the purchase of vaccines from unauthorised sources, including online sources, and from unverified healthcare practitioners or anyone working outside the healthcare settings authorised to carry out vaccinations of the COVID-19 vaccine to the public.

13. While the focus is primary on the manufacture and supply of COVID-19 vaccines, there needs to be greater emphasis on intelligence gathering and preventive measures. Monitoring suspicious transactions in respect of the instruments and devices that are needed to produce and market falsified vaccines, including syringes, vials, caps and crimping tools, printmaking equipment and tools (for COVID-19 labelling and certificates), etc., provides valuable intelligence to prevent offending and also the opportunity for intelligence-led law enforcement operations and the subsequent prosecution on offenders. (Article 17).



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