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Proposal for a report on the falsification of medical devices

Note to the Committee of the Parties of the MEDICRIME Convention

The falsification of medical products poses a serious threat to public health. There is a growing illegal trade in **medicines** and **vaccines**, which also involves **medical devices**. Counterfeit **personal protective equipment** (masks, etc.), **medication administration systems** (infusion sets, etc.) and **surgical equipment** (drill bits, prostheses and implants, etc.) occasionally even make their way into operating theatres, hospitals and pharmacies in Europe and the United States.

Medical and surgical devices, subject to less stringent regulation than medicine, are a prime target for traffickers, as this diverse market offers many opportunities for fraud.

In 2010, the World Health Organisation estimated that **at least 8% of all medical devices in circulation around the world were counterfeit**,[1] but in reality, that proportion is probably higher. Eleven years later, the true scale of the threat is still unknown.

European Regulation 2017/745, which entered into force on 26 May 2021, aims to enhance the safety of medical devices in the European Union (EU). While this is a major step forward, the regulation will only apply to EU member states and could encourage traffickers to expand their lethal business beyond its borders **in non-member countries that have close ties with the EU** but less stringent legislation and fewer controls. The Covid-19 pandemic also showed that any state could be vulnerable in a crisis situation, even those with the most robust healthcare systems. In addition, the waves of shortages affecting countries in and outside the EU may encourage grey markets and illegal supply chains to emerge.

In response to this ever-growing danger, the **OPALS Foundation** and the **Foundation of the French Academy of Surgery** propose that the Committee of the Parties to the MEDICRIME Convention consider carrying out a **survey** and then drafting a **report on the falsification of medical devices** in the countries that have ratified the Convention, with a view to making a more accurate assessment of this threat, the vulnerabilities in pharmaceutical distribution channels that traffickers may exploit, the level of awareness among the relevant stakeholders (health and legal professionals, the police, the customs authorities, etc.), the legislative and regulatory weaknesses of the countries concerned and the advantages of the remedies offered by the Convention, while also promoting information sharing and judicial and technical co-operation against trafficking.

[1] http://www.who.int/medical_devices/global_forum/3rd_gfmd/againstcounterfittingforgingdocuments.pdf

This report could focus on four main points:

- **Drawing up a list of the most important cases of falsification of medical devices** in the Parties, which should include information on the context of the trafficking, its consequences for healthcare, the risks to which victims may be exposed and any legal proceedings initiated.
- **Analysing the regulations on medical devices** in force in the Parties to identify their strengths and weaknesses.
- **Assessing the transposition of the MEDICRIME Convention provisions** on the falsification of medical devices.
- **Asking the relevant stakeholders** (health and legal professionals, police, customs, etc.) how much they know about the phenomenon and the related risks.

Appropriate recommendations would be issued on the basis of the replies received from national authorities.