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Draft Concept note
Leakages and theft from the supply chain of medical products

The Council of Europe is preparing an expert report involving law enforcement and others to report on the leakages and thefts from the supply chain of medical products to determine how best the MEDICRIME Convention¹ could enable the prevention, detection, investigation and prosecution of such crimes.

The objectives of the report are *inter alia*:

- a) to identify the circumstances, including availability and choice of product types, in which medical products are lost to the supply chain through leakages and theft;
- b) the consequences to the public health system (undermining the system's security at point of loss and reintegration through infiltration in a falsified manner);
- c) the consequences to the criminal justice system (undermining the system's ability to adequately address such crimes), and
- d) to illustrate the need for national and international cooperation to address this truly transnational crime with a clear impact on public health;
- e) to identify the added value of the MEDICRIME Convention in the areas of investigation and judicial cooperation to prosecute the intentional behaviours involved that lead to the counterfeiting of medical products and similar crimes.

The Council of Europe took an early interest in addressing counterfeit medical products and similar crimes involving threats to public health, involving law enforcement, public health authorities, industry, and prosecutors. It focused on the criminalisation of certain acts, the protection of the rights of victims and the promotion of national and international co-operation. The work of law enforcement in the effective investigation of crimes involving medical products has been challenging in several Council of Europe member States, and across the globe, notably in terms of ensuring the requisite powers, technical skills and knowledge involving medical products. Courts have faced challenges when it comes to identifying an appropriate and relevant legal basis on which to adjudicate.

The report will explore the extent to which the value of the medical product in circumstances of poor governance and security, and an inadequate criminal justice system, when combined, result in a favourable environment for criminal groups to exploit and at low risk to detection and prosecution. Moreover, it will examine reports of leakage and theft in different countries

¹ *Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health*, CETS No. 211, Moscow, 28 October 2011.

with a view to determining whether these combined circumstances are common in all situations. It will report on the mechanisms used by criminal groups to infiltrate the legitimate supply chain for medicinal products with the diverted products and the extent to which, if any, that falsified medical products have been comingled with them, or otherwise associated with the same criminal groups.

Emphasis will be put on identifying what criminal laws, or other laws, and mechanisms have been deployed by law enforcement and prosecutors to address these specific crimes. Both law enforcement and prosecutors face the argument that crimes involving medical products should be regarded as mere regulatory breaches requiring a regulatory response and are not sufficiently serious to be addressed by the criminal law. Health product regulators face the prospect that they are ill-equipped to combat organised criminal behaviour on matters that are beyond their statutory remit to guarantee the quality, safety and efficacy of medical products. The report will seek to determine in the investigated instances of leakage and theft of medical products whether there were unused resources available to investigators and prosecutors and those tools that have been developed but may not yet be implemented, such as the MEDICRIME Convention and the Palermo Convention.²

The role played by international cooperation to assist law enforcement and judicial cooperation to rapidly exchange vital investigative information facilitating evidence collection in other States on these crimes will be analysed to see whether the mechanism used was sufficiently responsive in the circumstances of these crimes. It will also consider whether a dedicated MEDICRIME 24/7 network could better facilitate cooperation in these circumstances.

The impact of victims, where this can be ascertained within the objectives of this report, will be considered to see what lessons can be learned concerning their protection. The report conclusions will draw from the circumstances and outcomes of crimes involving leakages and theft of medical products with a view to make recommendations on how to better deter organised criminal groups from engaging in these specific crimes. It will focus on the gaps found in existing legislation and training that need to be filled to prevent such leakage and theft more effectively, on how to better prepare for the investigation and prosecution of these crimes, all with a view to protecting public health.

² United Nations, *United Nations Convention against Transnational Organised Crime and the Protocols Thereto*, New York, 15 November 2000 (adopted by resolution A/RES/55/25).