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**World crime trends and emerging issues and responses in
the field of crime prevention and criminal justice****Countering fraudulent medicines, in particular their
trafficking****Report of the Executive Director***Summary*

The present report was prepared pursuant to Commission on Crime Prevention and Criminal Justice resolution 20/6, entitled “Countering fraudulent medicines, in particular their trafficking”. The report provides an overview of the activities of the United Nations Office on Drugs and Crime to counter fraudulent medicines, in particular their trafficking, including assisting Member States in building capacity to disrupt and dismantle the organized criminal networks engaged in all stages of the illicit supply chain, in particular distribution and trafficking, and utilizing the experiences, technical expertise and resources of relevant regional and international organizations to create synergies with interested partners.

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I. Introduction

1. At its twentieth session, in April 2011, the Commission on Crime Prevention and Criminal Justice adopted resolution 20/6, on countering fraudulent medicines, in particular their trafficking, in which it invited the United Nations Office on Drugs and Crime (UNODC) to continue to conduct research on the modalities of transnational organized crime, including its involvement in the issue of fraudulent medicines; encouraged UNODC to identify key Member States in the most affected regions and to provide corresponding technical assistance to such Member States, upon request; and requested the Office to assist Member States in building capacity to disrupt and dismantle the organized criminal networks engaged in all stages of the illicit supply chain, in particular distribution and trafficking, to better utilize the experiences, technical expertise and resources of each organization and to create synergies with interested partners.
2. Fraudulent medicines, ranging from cough syrup for children to antiviral drugs and cancer medications, have become a global problem and present a significant public health risk.
3. The supply chain for medicines operates at the global level; therefore, effectively detecting and combating the introduction of fraudulent medicines along complex supply routes requires concerted effort and understanding at all levels. The production of and trafficking in fraudulent medicines are global; no region or country is immune from the problem.
4. Fraudulent medicines have become an important source of income for organized criminal groups. Large profits can be made from them and, in poorly regulated markets, the risks for perpetrators are low. As with other forms of crime, criminal groups involved in the production of and trafficking in fraudulent medicines exploit gaps in legal and regulatory frameworks, weaknesses in capacity and the lack of resources among regulatory, enforcement and criminal justice officials. As with other forms of trafficking, corruption of public officials is also involved in the trafficking of fraudulent medicines.
5. Until the twentieth session of the Commission on Crime Prevention and Criminal Justice, the focus of the international community had been on the health and regulatory aspects of fraudulent medicines, and the crime and criminal justice perspectives of the problem had received less attention. In its resolution 20/6, the Commission noted with concern the involvement of organized criminal groups in all aspects of trafficking in fraudulent medicines.
6. The present report contains information on activities undertaken by UNODC to assist Member States in countering fraudulent medicines, in particular their trafficking, and in addressing the challenges to advancing work in this area. The report also contains recommendations for consideration by the Commission on Crime Prevention and Criminal Justice.

II. Challenges in successfully countering trafficking in fraudulent medicines

7. The absence of agreement on the definition of terms presents one obstacle to concrete action by the international community. Although relevant stakeholders aim to ensure reliable access to safe and effective medicines and to take action against trafficking in fraudulent medicines, there are a number of issues on which no common position has been reached. This has limited the effectiveness of the international community's response. For example, stakeholders may refer interchangeably to "counterfeit", "illicit", "fake", "substandard" or "falsified" medicines.

8. Specific difficulties arise with regard to the term "counterfeit", on the use of which there is no agreement among States, especially because use of the term may give rise to issues related to intellectual property rights. Concerns have been raised that the use of the broader definition of "counterfeit" might threaten the trade in generic medicines of assured quality, upon which many people in developing countries depend, owing to their lower prices and greater accessibility. However, in the view of most stakeholders, there is no difference between generic and proprietary medicines, and both are at risk of being falsified.

9. The World Health Organization (WHO) uses the expression "substandard/spurious/falsely labelled/falsified/counterfeit medical products" to designate products that may raise public health concerns and that require international cooperation for the purposes of prevention and control.

10. In its resolution 20/6, the Commission stressed that, without prejudice to other accepted definitions, "fraudulent" medicines, usually referred to as "falsified medicines", include purported medicines whose contents are inert, are less than, more than or different from what is indicated, or have expired.

11. Like other serious crimes, actions that may contribute to the production of or trafficking in fraudulent medicines require a requisite level of criminal intent (*mens rea*) or criminal negligence, and when such intent or negligence exist, those actions should be treated as serious crimes and be sanctioned with corresponding penalties, taking into account the damage caused (such as death, serious injury or risk of endangering the health of a large number of persons) and the status of the perpetrator (for example, authorized operator, health-care professional or criminal group), among other issues.

12. While there are a number of operational mechanisms, set up under the aegis of WHO, many countries lack adequate legal and regulatory frameworks. Moreover, in countries in which there are laws that deal specifically with the issue, the penalties foreseen may not be commensurate with the seriousness of the crime.

III. Existing frameworks and the complementary role that can be played by the United Nations Convention against Transnational Organized Crime

13. In 2006, WHO launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), aimed at developing coordinated networks among countries to halt the production, trading and selling of fake medicines through partnerships between major anti-counterfeiting actors, including international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers associations and drug regulatory authorities.

14. In 2011, the sixty-fifth World Health Assembly established a new member State mechanism, open to all WHO member States and, where applicable, regional economic integration organizations, to promote international collaboration, policy formulation and capacity-building to prevent and control substandard/spurious/falsefully labelled/falsified/counterfeit medical products from the standpoint of public health (and not trade or intellectual property). The mechanism held its first session in Buenos Aires from 19 to 21 November 2012. Discussions on the workplan and steering committee are to continue in 2013.

15. Reference should also be made to the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health, which was opened for signature on 28 October 2011. The Convention is aimed at preventing and combating threats to public health by providing for the criminalization of certain acts; protecting the rights of victims of the offences established under the Convention; and promoting national and international cooperation against such offences. It does not seek to address issues concerning intellectual property rights.

16. The Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health also establishes a framework for cooperation among the competent health, police and customs authorities at both the national and international levels; crime prevention measures involving the private sector; and the effective prosecution of crime and protection of victims and witnesses.

17. The United Nations Convention against Transnational Organized Crime could serve as a useful tool to counter trafficking in fraudulent medicines. The Commission on Crime Prevention and Criminal Justice, in its resolution 20/6, underscored the potential utility of the Convention in reinforcing international cooperation in the fight against trafficking in fraudulent medicines, including their illicit production and distribution, through, inter alia, mutual legal assistance, extradition and the recovery of the proceeds of crime.

18. The lack of harmonized legal frameworks in many countries, in particular the absence of dual criminality, prevents adequate investigation and prosecution, resulting in impunity for criminals. Furthermore, even when national legislation exists, enforcement and sanctions may remain weak.

19. Articles 2, 3 and 37 of the Organized Crime Convention provide the scope for applying the Convention to serious offences that are transnational in nature and involve an organized criminal group. There is a compelling need to treat trafficking

in fraudulent medicines as a serious offence established in accordance with the Organized Crime Convention.

20. Using the Convention as the legal basis, UNODC can assist States, upon request, by: (a) raising awareness of the issue of fraudulent medicines, in particular their trafficking, among policymakers and criminal justice sector officials; (b) supporting the development and strengthening of national legislation; (c) enhancing the capabilities of border, customs, other law enforcement and regulatory officials to more effectively investigate those crimes and to cooperate at the national and international levels; (d) developing and implementing effective regimes to counter money-laundering in order to trace, freeze and confiscate the proceeds from those crimes; and (e) training prosecutors and judicial officials, as well as officials from central authorities, to more effectively prosecute those crimes and to cooperate for the purposes of extradition, mutual legal assistance and the recovery of assets.

IV. Research activities on the involvement of transnational organized crime in trafficking in fraudulent medicines

21. In its resolution 20/6, the Commission on Crime Prevention and Criminal Justice invited UNODC, in consultation with Member States and in cooperation with other competent international organizations, to continue to conduct research on the modalities of transnational organized crime, including its involvement in the issue of fraudulent medicines, so as to provide a better framework of knowledge for effectively preparing evidence-based responses to that illicit trade.

22. The full extent of the phenomenon of fraudulent medicines remains unclear, as statistics on the quantities trafficked and the number of deaths related to such medicines are extremely difficult to obtain.

23. UNODC continues to conduct research on the issue of fraudulent medicines as part of its work on the modalities of transnational organized crime, so as to provide a better basis for preparing evidence-based responses to the illicit trade in such medicines. In 2012, UNODC, in consultation with Member States and in cooperation with other competent international organizations, including members of the United Nations system task force on transnational organized crime and drug trafficking as threats to security and stability, analysed the issue of trafficking in fraudulent medicines as part of two regional transnational organized crime threat assessments: one on West Africa (published in February 2013) and one on East Asia and the Pacific (forthcoming). In *Transnational Organized Crime in West Africa: A Threat Assessment*, UNODC estimated that at least 10 per cent of the imported medicines circulating in West Africa were fraudulent, representing at least \$150 million in annual imports. As requested by Member States, UNODC will further develop its research work on the transnational organized crime dimensions of the problem at the global level.

V. Technical assistance activities promoting the use of the United Nations Convention against Transnational Organized Crime

24. The Commission on Crime Prevention and Criminal Justice, in its resolution 20/6, requested UNODC, in accordance with its mandate and in close cooperation with other United Nations bodies and international organizations, such as the International Narcotics Control Board, WHO, the World Customs Organization and the International Criminal Police Organization (INTERPOL), as well as relevant regional organizations and mechanisms, national agencies that regulate medicines and, where appropriate, the private sector, civil society organizations and professional associations, to assist Member States in building capacity to disrupt and dismantle the organized criminal networks engaged in all stages of the illicit supply chain, in particular distribution and trafficking, to better utilize the experiences, technical expertise and resources of each organization and to create synergies with interested partners.

25. In November 2011, UNODC, together with the Government of France, held a regional meeting on countering fraudulent medicines in Belgrade. In addition, UNODC hosted a technical conference on trafficking in fraudulent medicines in Vienna on 14 and 15 February 2013. Both activities were funded by an extrabudgetary contribution from the Government of France.

26. The main objectives of the technical conference were to broaden understanding about the crime aspect of trafficking in fraudulent medicines through the sharing of experiences by national, regional and international authorities and organizations, as well as by public and private sector entities, and to identify gaps and to foster effective international collaboration.

27. The sessions of the technical conference covered the following issues related to the illicit production, distribution and trafficking of fraudulent medicines: (a) challenges in addressing the problem; (b) national and regional perspectives, initiatives and responses; (c) perspectives from non-governmental organizations and business associations; and (d) regulatory and law enforcement investigations, training and cooperation. Experts highlighted the complexity of the problem from a legal, regulatory, law enforcement and criminal justice perspective.

28. The following points were raised during the discussions and were summarized by the Chair at the closure of the expert conference:

(a) Fraudulent medicines are a transnational crime problem with actors in different countries participating in different aspects of their production and trafficking. Moreover, in addition to using traditional drug trafficking methods, new means and methods are being employed, including the exploitation of free trade zones by criminal groups;

(b) Given the global scope of the problem, multisectoral, regional and international cooperation is needed among all stakeholders, including the private sector and civil society;

(c) There is a strong need for reliable data and independent research to assess the magnitude and dimension of the problem and to support evidence-based

policies. The international community could contribute to the collection, sharing and analysis of information relating to trafficking in fraudulent medicines and related crimes;

(d) There is a need for awareness-raising among the public, relevant practitioners and criminal justice actors and regional and international regulatory agencies concerning criminal involvement in the production of and trafficking in fraudulent medicines;

(e) Adequate criminalization provisions need to be in place in order for criminal justice actors to effectively investigate and prosecute the production of and trafficking in fraudulent medicines. Penalties of four or more years' imprisonment should be introduced so that the Organized Crime Convention could be used as a basis for international cooperation;

(f) The Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health could be used as a tool to review and strengthen legal frameworks;

(g) Capacity-building efforts should target countries that are less developed and more vulnerable and special attention should be given to anti-infective drugs (i.e. life-saving medicines such as antimalarials, antibiotics and antiretrovirals);

(h) Training related to issues concerning fraudulent medicines should be provided to criminal justice actors, in particular law enforcement officials, prosecutors and judges. Support for national and regional forensic capacities, as well as capacities for the collection, sharing and analysis of intelligence, should be fostered;

(i) The international community should make use of existing practical tools and networks and should strengthen the links between health and crime prevention strategies;

(j) The use of technology to detect and investigate trafficking in fraudulent medicines is crucial and the international community should continue to support new technologies and to assist countries in obtaining the equipment necessary for detecting fraudulent medicines;

(k) Inter-agency cooperation, coordination and networks, in particular between regulatory and law enforcement agencies, are needed. A single point of contact could be nominated in law enforcement and specialized prosecution units that deal with drugs or organized crime;

(l) It could be beneficial for States to establish working groups comprising all national stakeholders in order to develop and implement national strategies and action plans to prevent and combat the production of and trafficking in fraudulent medicines. Relevant regional and international agencies could support and facilitate such strategies and action plans.

VI. Recommendations

29. In order to prevent and combat trafficking in fraudulent medicines, the Commission on Crime Prevention and Criminal Justice may wish to invite Member States to consider taking the following measures:

(a) Convene joint training seminars involving law enforcement agencies, such as police, border police, customs and other relevant actors, to promote greater understanding and cooperation at the national, regional and international levels;

(b) Provide UNODC with information and statistics on the trafficking of fraudulent medicines involving, in particular, organized criminal groups;

(c) Inform UNODC of technical assistance needs such as training programmes and legislative drafting assistance in order to more effectively prevent and combat trafficking in fraudulent medicines;

(d) Use relevant databases and tools already developed by competent regional and international organizations such as the European Police Office (Europol), INTERPOL, the World Customs Organization and WHO to assist in the fight against trafficking in fraudulent medicines;

(e) Make use of the provisions of the Organized Crime Convention to more effectively investigate and prosecute activities of organized criminal groups related to the production of and trafficking in fraudulent medicines.

30. The Commission on Crime Prevention and Criminal Justice may wish UNODC to consider developing additional criminal justice tools and training programmes that could be used to assess and strengthen legal and regulatory frameworks and enhance the building of technical capacity in the area of trafficking in fraudulent medicines.

31. The Commission on Crime Prevention and Criminal Justice may wish to encourage Member States to provide UNODC with extrabudgetary resources to implement Commission resolution 20/6, in particular to enable UNODC to adequately respond to requests for technical assistance in this thematic area.