



# ***International Standards Applicable to the Illicit Trade in Medical***

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## DEFINITIONS - WHO

- **Substandard**, also called "out of specification", are authorized medical products that fail to meet either their quality standards or specifications, or both.
- **Unregistered/unlicensed**: medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
- **Falsified** medical products deliberately/fraudulently misrepresent their identity, composition or source.

# THE RANGE OF CRIMES INVOLVED

- Counterfeiting/falsification
- Sale of unregistered/unlicensed products
- Deliberate traffic in substandard/degraded/unlicensed products
- Illegal storage and marketing
- False documentation
- Stolen cargo/products
- Diversion
- Illegal export/import/smuggling
- Sabotage
- Money laundering
- Corruption
- Other financial crimes: tax evasion, terrorism finance, sanctions violations

# WHO IS INVOLVED

- Individuals
- Criminal groups
- Illegal manufacturers
- Legal manufacturers
- Public officials
- Health professionals
- Logistics personnel
- Traders
- State actors

# COUNTERFEIT MEDICINES – THE PROBLEM

## ❑ Global Challenge

- Significant increase in counterfeit pharmaceuticals and medical products (diagnostics, PPE, etc)
- Disproportionately affects LMI countries
- Targets vulnerable populations (e.g., cancer, malaria patients)

## ❑ Financial Incentives

- Estimated annual market size is \$4 B
- Annual growth of about 20%

## ❑ Supply Chain Issues

- Number of “weak links” in the drug supply chain

## ❑ Consumer Awareness and Incentives

- Majority of consumers are not aware of the problem (e.g., legitimacy of Internet pharmacies, across border purchases, cheaper prices, etc)

## ❑ COVID-19 Pandemic

- The issue is exacerbated in a pandemic situation, especially with inequalities in health care, promise of “quick fixes” and cheaper goods, misinformation

# EFFECTS

- undermines public health as hundreds of thousands of people die; millions suffer ill-health or go untreated annually
- leads to long-term drug resistance - this is particularly critical in the context of pandemics
- at least \$75 billion to governments and companies annually
- financial loss to individual consumers
- damages company brands and reputation
- distorts competition
- disrupts national or regional economies
- threatens rule of law and security
- wastes funds targeting vulnerable populations and contributes to health inequity around the world

# CURRENT CHALLENGES

## ❑ Lack of Universal Standards

- No global strategy to the problem
- Third world versus first world problem
- Secrecy, data not shared

## ❑ Difficulty in Broad Adoption

- There is no one-size-fits-all solution
- Government oversight (border control, regulatory authorities, etc) versus consumer empowerment

## ❑ Cost Structure

- Who pays – pharma company, third party, consumers?
- What is a reasonable cost?

## ❑ Responsibility and Accountability

- Even if the technology exist, will it be used?
- Bad actors are not adequately prosecuted (corruption, etc)
- Penalties do not deter criminal behaviors

# ADDITIONAL CHALLENGES

- Emergency
- Criminogenic Asymmetries (legal, economic, cultural, technological, political, knowledge, health, etc.)
- De-globalization
- Balance of role and responsibility of states and private sector



# CONTRIBUTING FACTORS

- Poor governance in many countries
- Corruption of public officials, law enforcement and regulatory personnel, company employees, health professionals
- Supply-demand asymmetries
- High prices for certain drugs incentivize bad actors
- Participation of organized criminal groups as well as legitimate actors
- Imperfect knowledge on modus operandi and social organization of criminal networks
- Weak regulatory oversight of the supply chain – esp. the “last mile to the patient”
- Need for stronger risk-based inspections and post market surveillance
- Coordination among stakeholders - especially with Customs authorities
- Low reporting to National Medical Regulatory Authorities from public and healthcare professionals
- Weak laboratory capacity, esp. in lower-income countries
- Reluctance to share data and relevant information by companies, regulatory and law enforcement agencies
- Lack of adequate national and international legal framework
- Mistrust to public institutions and big pharma
- Market failure; inadequate government/private sector balance conducive to ill-preparedness, lousy response and growing inequalities that serve no one and undermine the common good

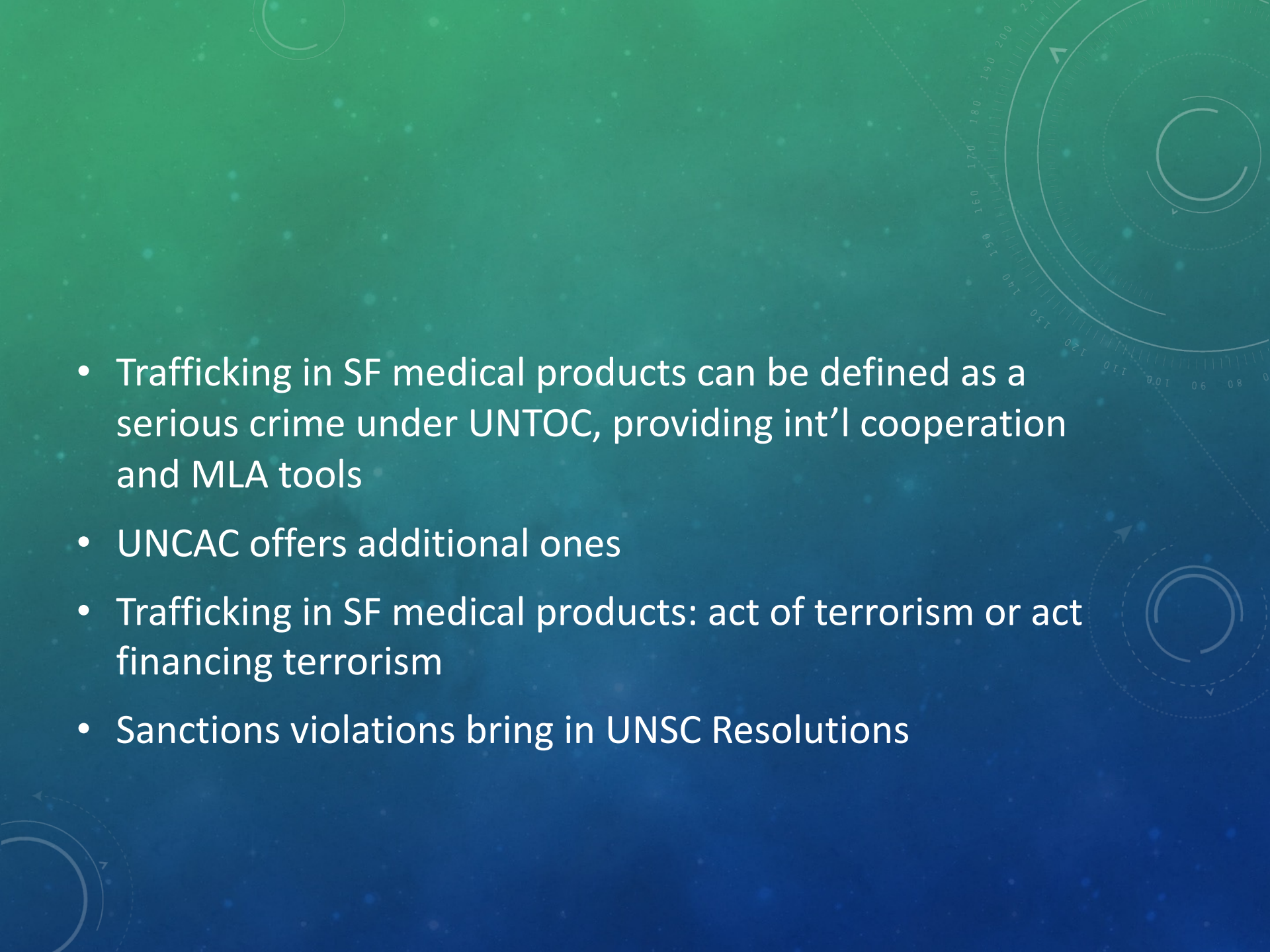
# APPROACHES TO PREVENTION, DETECTION, RESPONSE

- Technology
- Law
- Institutional
- Awareness
- Educational
- Governance

- **Normative harmonization**
- Address trust-deficit, improve quality of governance
- Data and better knowledge
- Better and accessible authentication technologies
- Address criminogenic asymmetries in price, availability, access, proper storage, supply chain security
- P-P-NGO-IO-Academic initiatives

# CREATIVE TREATMENT OF SERIOUS CRIME PROBLEMS (BINDING STANDARDS)

- Specific convention (Medicrime)
- Corruption (UNCAC)
- Organized crime (UNTOC)
- Terrorism finance
- UN sanctions regimes
- Human rights
- Assets and taxes
- Money laundering

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- Trafficking in SF medical products can be defined as a serious crime under UNTOC, providing int'l cooperation and MLA tools
  - UNCAC offers additional ones
  - Trafficking in SF medical products: act of terrorism or act financing terrorism
  - Sanctions violations bring in UNSC Resolutions

# APPLICABLE INTERNATIONAL STANDARDS

- Council of Europe: Medicrime Convention – 21 ratifications (20 signatures without ratification)
- UNTOC (2000) – 191 ratifications
- UNCAC(2003) – 189 ratifications
- UN Convention for the Suppression of the Financing of Terrorism (1999) – 189 ratifications
- UN Security Council Resolutions 1814 (2008), 1816 (2008), 1838 (2008), 1844 (2008), 1846 (2008), 1851 (2008), 1897 (2009) 1918 (2010) – all UN Member States

# MEDICRIME CONVENTION – COUNCIL OF EUROPE

- **21 States Parties**
- **Benefits**
  - Harmonized definitions for «pharmaceutical crime»
  - Sanctions to deter such offenses
  - International co-operation in Europe and beyond
  - Protect rights of victims
- Mandates the criminalization of
  - the manufacturing of falsified medical products (i.e. the intentional manufacturing of counterfeit or adulterated medical products, active substances, excipients, parts, material and accessories) (Art. 5)
  - the supply and trafficking of medical products (including brokering, keeping in stock, importing and exporting) (Art. 6)
  - the keeping in stock for supply, import, export and placing in the market of unauthorized medical products or non-compliant medical devices (Art. 8)
  - the falsification or tampering of documents (Art. 7)

## ART. 8: MANDATORY CRIMINALIZATION OF “SIMILAR CRIMES INVOLVING THREAT TO PUBLIC HEALTH”

- the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:
  - i. medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or
  - li. medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;
- the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party
- aiding or abetting the commission of any of the offences established in accordance with this Convention
- the intentional attempt to commit any of the offences established in accordance with this Convention



- Medicrime lays down a framework for national and international co-operation between the competent health, sports, research, police and customs authorities on both national and international levels, measures for crime prevention by also involving the private sector, and the effective prosecution of crime and the protection of victims and witnesses

### **1. Central Authorities**

### **2. Law enforcement authorities + Legal actors (judges/prosecutors)**

### **3. Investigation**

### **4. International cooperation in criminal matters**

## UNTOC Legislative Guide

# 联合国打击跨国有组织 犯罪公约及其议定书 实施立法指南



联合国

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# UNTOC

- 191 Parties
- Requires
  - Organized criminal group (3 or more people, ongoing basis, for profit)
  - Transnational activity
  - Commission of “serious” crime (imprisonment of 4 years or more)
- Many countries do not have adequate legislation, capacity or political will

## FOUR MAIN OFFENSES

- Participation in an organized criminal group (Art. 5)
  - Laundering of proceeds of crime (Art. 6)
  - Corruption (Art. 8)
  - Obstruction of justice (Art. 23)
- 
- Transnationality and involvement in an organized criminal group need/should not be elements of offences in domestic law (Art. 34. 2).

# THESE ARE POTENTIALLY APPLICABLE

- If traffic of SF medical products is a “serious crime” under national law and
- The activity crosses national borders and
- Is committed by those participating in an organized criminal group or
- Traders/traffickers launder the proceeds of their crime or
- Traders/traffickers bribe or offer/attempt to bribe officials or
- they obstruct justice

# ORGANIZED CRIMINAL GROUP ART. 2

- structured group
- of three or more persons
- existing for a period of time
- acting in concert
- aim of committing:
  - serious crimes or UNTOC offences
  - to obtain direct or indirect financial or other material benefit (Art. 2. a)

# STRUCTURED GROUP (ART. 2 C)

- Not necessarily formal organization, membership or structure, but
- more than just “...randomly formed for the immediate commission of an offence”

## OC GROUP PARTICIPATION

- agreeing to commit a *serious crime* for financial or material benefit
- or
- knowingly taking part in criminal or related activities of an *organized criminal group* to contribute to criminal aim
- different approaches to conspiracy, association etc. possible. States must see that domestic law covers all *serious crimes* committed by organized groups



# MONEY LAUNDERING (ART. 6)

- Conversion or transfer to conceal criminal origins
- Concealment of nature, source, location, disposition, movement or ownership
- Knowing acquisition of proceeds\*
- Participation, association, conspiracy, attempts, aiding, abetting and facilitating\*

\*to the extent these are compatible with the fundamental legal principles of States Parties

# CORRUPTION (ART. 8)

- Mandatory
  - promise, offer, give, solicit or accept
  - any undue advantage to/by a public official
  - to act or refrain from acting
  - any matter relating to official's public duties
  - participation as an accomplice
- Optional
  - Bribe foreign or international public servants
  - Other forms of corruption (abuse of power, abuse of function, illicit enrichment, etc.)

# OBSTRUCTION OF JUSTICE (ART. 23)

- Using force, threats or intimidation or
- promising, offering or giving undue advantage
  - to interfere with giving of evidence or testimony
  - to interfere with exercise of duties of judicial or law-enforcement official
  - in connection with proceedings on any Convention offence

## TRANSNATIONALITY (ART. 3.2)

- It is committed in more than one State
- It is committed in one State but a substantial part of its preparation, planning, direction or control takes place in another State
- It is committed in one State but involves an organized criminal group that engages in criminal activities in more than one State; or
- It is committed in one State, but has substantial effects in another State

# EVEN WIDER SCOPE

- article 16 (extradition): the person who is the subject of the request for extradition is located in the territory of the requested State party
- article 18 (mutual legal assistance): victims, witnesses, proceeds, instrumentalities or evidence of offences are located in the requested State party

## SERIOUS CRIME (ART. 2B)

- Conduct constituting an offence punishable by a maximum deprivation of liberty of at least four years or a more serious penalty

# ORGANIZED CRIMINAL GROUP (ART. 2A)

- A structured group of three or more persons existing for a period of time
- Acting in concert with the aim of committing one or more serious crimes or offences established in accordance with the Convention
- to obtain, directly or indirectly, a financial or other material benefit

# HELPFUL PROVISIONS

- Seizure and Confiscation of proceeds
- International cooperation
- Extradition
- Mutual legal assistance
- Special investigative techniques
- Joint investigations
- Training and technical assistance



# OTHER FORMS OF COOPERATION (ART. 27)

- Establish and enhance channels of communication
- cooperate in inquiries concerning the identity, whereabouts and activities of suspects; the movement of proceeds of crime or instrumentalities
- exchange information on:
  - specific means and methods used by organized criminal groups
  - general trends, analytical techniques, definitions, standards and methodologies

# ISSUES

- Must cross borders – domestic offenses with domestic effects by local group are not transnational
- Low-level offenses may not constitute ‘serious crime’
- If one or two persons commit the offense, it is not committed by an organized criminal group
- States must criminalize the act of traffic in SF medical products and contribute to the prosecution of suspected offenders (esp. their own nationals)
- Wider awareness and preparedness to use the UNTOC (or UNCAC, when appropriate) against SF medical products



NATIONS UNIES  
Office contre la drogue et le crime

# GUIDE LÉGISLATIF POUR L'APPLICATION DE LA CONVENTION DES NATIONS UNIES CONTRE LA CORRUPTION



## Liste des experts

Les experts dont les noms suivent ont participé à l'élaboration du guide

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# UNCAC

- 189 States Parties
- Commission of convention offenses
  - Bribery of public officials
  - Bribery of foreign public officials
  - Obstruction of justice
  - Embezzlement in public or private sector
  - Money laundering
  - Abuse of function
  - Trading in influence
  - Illicit enrichment
  - Private-to-private corruption

# CHAPTER III: CRIMINALIZATION AND LAW ENFORCEMENT

## Mandatory Offences

- Bribery of National Public Officials (Art. 15)
- Active Bribery of Foreign Public Officials (Art.16, para.1)
- Embezzlement, Misappropriation or Other Diversion of Property (Art. 17)
- Laundering of proceeds of crime (Art. 23)
- Obstruction of Justice (Art. 25)
- Participation in such offences (Art. 27, para. 1)

## Optional Offences

- Passive Bribery of Foreign Public Official (Art.16)
- Trading in Influence (Art. 18)
- Abuse of Functions (Art. 19)
- Illicit Enrichment (Art. 20)
- Bribery in Private Sector (Art. 21)
- Embezzlement of Property in Private Sector (Art. 22)
- Concealment (Art. 24)
- Attempt / preparation of UNCAC offences (Art.27, paras. 2-3)

## RELEVANT UNCAC ARTICLES ON BRIBERY

- Article 15: **Bribery of National Officials**
- Article 16: **Bribery of International Officials**
- Article 21: **Bribery in the Private Sector**

# TERRORISM AND SANCTIONS

- Terrorism finance
- Proliferation finance
- Sanctions regimes

# UN INTERNATIONAL CONVENTION FOR THE SUPPRESSION OF THE FINANCING OF TERRORISM - ART. 2

- someone commits the offense of terrorist financing if s/he “by any means, directly or indirectly, unlawfully and willfully, provides or collects funds with the intention that they should be used or in the knowledge that they are to be used, in full or in part, in order to carry out a) an act which constitutes an offence within the scope of and as defined in one of the treaties listed in the annex” [nine universal instruments against terrorism] or
- b) any act “intended to cause death or serious bodily injury to a civilian, or to any other person not taking an active part in the hostilities in a situation of armed conflict, when the purpose of such act, by its nature or context, is to intimidate a population, or to compel a government or an international organization to do or to abstain from doing any act”



# UNSCR 1373 2001

- 1. *Decides that all States shall:*
- (a) Prevent and suppress the financing of terrorist acts;
- (b) Criminalize the wilful provision or collection, by any means, directly or indirectly, of funds by their nationals or in their territories with the intention that the funds should be used, or in the knowledge that they are to be used, in order to carry out terrorist acts;
- (c) Freeze without delay funds and other financial assets or economic resources of persons who commit, or attempt to commit, terrorist acts or participate in or facilitate the commission of terrorist acts; of entities owned or controlled directly or indirectly by such persons; and of persons and entities acting on behalf of, or at the direction of such persons and entities, including funds derived or generated from property owned or controlled directly or indirectly by such persons and associated persons and entities;

# AUTONOMOUS OBLIGATION

- (d) Prohibit their nationals or any persons and entities within their territories from making any funds, financial assets or economic resources or financial or other related services available, directly or indirectly, for the benefit of persons who commit or attempt to commit or facilitate or participate in the commission of terrorist acts, of entities owned or controlled, directly or indirectly, by such persons and of persons and entities acting on behalf of or at the direction of such persons;

# SANCTIONS

- The UNSCRs most relevant to a review of financial vigilance measures are:
- UNSCRs 1540, 1673, 1810, 1887, 1977 on non-state actor proliferation;
- UNSCRs 1695, 1718, 1874 on DPRK; and
- UNSCRs 1696, 1737, 1747, 1803, and 1929 on Iran
- 1533 (2004) on the Democratic Republic of the Congo
- 1591 (2005) on the Sudan
- 2206 (2015) on South Sudan
- 2127 (2013) on the Central African Republic
- 1970 (2011) on Libya
- 2374 (2017) on Mali
- 2140 (2014) on Yemen

# PROVIDE FOR

- export- and border-control issues
- financial controls and vigilance;
- activity-based financial prohibitions;
- specific vigilance measures and actions on designated banks;
- freezing of assets;
- international cooperation and information sharing; and
- financial and technical assistance.

# CONCLUSION: OPTIONS GOING FORWARD

- Broader ratification and strengthening of the Medicrime convention
- Ensure UNTOC can apply
- Smart application of UNCAC and other standards where virtually all countries have legal basis for collaboration



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