

Smuggling of Fraudulent Medicines:

A field guide for frontline officers



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This publication contributes to Sustainable Development Goal 16 that seeks to: “Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels”



The Sustainable Development Goals are the blueprint to achieve a better and more sustainable future for all. They address the global challenges we face, including those related to poverty, inequality, climate, environmental degradation, prosperity, and peace and justice. The Goals interconnect and in order to leave no one behind, it is important that we achieve each Goal and target by 2030.

It is estimated that 1 in 10 drugs sold in developing countries is fake or substandard, leading to tens of thousands of deaths every year, particularly amongst children. As much of 50% of drugs sold online drugs are also fake as are much of the medicines sold by street vendors.

The smuggling of fraudulent medicines is a huge criminal problem estimated as being worth as much as \$30 billion per year. These sales have been linked to organised crime and terrorist groups and also facilitate other crimes such as fraud, identity theft and money laundering.

The smuggling of fraudulent medicines is an insidious crime that targets the poorest members of our global community. It is the developing world which suffers the most from the smuggling of fraudulent medicine and the devastating effects it can have on communities.

The smuggling of fraudulent medicines is also a huge problem in South East Asia due to its proximity to the largest suppliers of fraudulent medicines, India and China. Successful detection of smuggled fraudulent medicines can save thousands of lives in your country, even the lives of family and friends.

You should carry this field guide with you while you are on duty. It contains quick-reference tools to address situations you are likely to experience in the course of your duty.

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1. WHAT ARE FRAUDULENT MEDICINES

Fraudulent medicines are medicines which are deliberately and fraudulently mislabeled with respect to identity and/or source and marketed with the intent to deceive. The fraudulent supply of medicines can apply to both branded and generic products.

Generally, fraudulent medicines may include:

- Medicines with the wrong ingredients.
- Medicines without active ingredients.
- Medicines with incorrect quantities of active ingredients.
- Counterfeit active/bulk ingredients.
- Counterfeit finished medicines.
- Unregulated diverted medicines.
- Counterfeit labelling.
- Mislabeled substances.

Common medicines that targeted by criminal organizations involved in smuggling fraudulent medicines include:

- Anti-malaria
- HIV
- Erectile dysfunction
- Antibiotics
- Cardiovascular
- Tuberculosis

Location where fraudulent medicines are manufactured include:

- India
- China
- United States
- Russia



2. INTERNATIONAL LEGAL INSTRUMENTS

To date there is no international instrument that is universal in scope and would provide a unanimously accepted definition of the falsification of medicines. Such a basis would provide a basis for preventive measures and the fight against the smuggling of fraudulent measures.

There are several local conventions that address wider counterfeiting of goods, including medicines including the European Union. However, there is still some distance to go to creating a universal agreement.

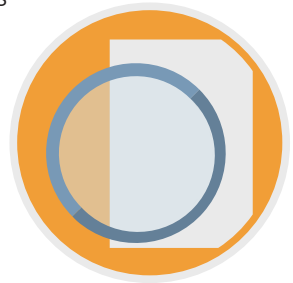
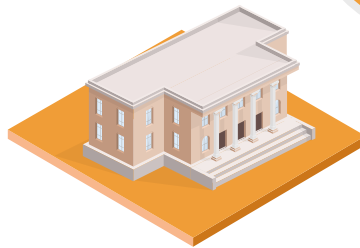


3. NATIONAL LEGISLATION.

In many countries there are not one, but several overlapping pieces of legislation or government decrees that may be relevant to the investigation of fraudulent medicines. In some countries the law may also not be as clear in relation to the criminality of the smuggling of fraudulent medicines.

It is important that you understand your domestic legislation and your departments roles and responsibilities as this may impact on the admissibility of any evidence you collect and your ability to exercise your powers. You should keep yourself up to date with the legislation relating to the smuggling of fraudulent medicines in your jurisdiction.

During an investigation into smuggling fraudulent medicines, and in particular transnational smuggling, several different agencies may play a role. An importation of fraudulent medicines into your country may fall under the jurisdiction of the Customs Department assisted by the Police and/or the relevant Health Departments whereas domestic trade in fraudulent medicines may only require input from the Health Department or Police. Other crimes arising from the smuggling of fraudulent medicines such as money laundering and corruption may be the responsibility of the Police or a dedicated anti-corruption agency.



4. INVESTIGATING THE SMUGGLING OF FRAUDULENT MEDICINES.

Investigating the smuggling of fraudulent medicines is generally like the investigation of any other crime. Often these investigations will be reactive, such as a result of a seizure. Others may be proactive, such as where you are targeting an organised criminal network or receive information from an informant. Irrespective of the type of investigation you undertake there are several important things to consider, including:

- Have I identified the fraudulent medicines subject to my investigation?
- Have I confirmed that the medicine is fraudulent?
- Do I need to wait for the medicine to be forensically analysed before I can take action?
- Do I have a legal basis for my investigation?
- Have I identified the offences that have been/suspect of being committed?
- Do I have sufficient resources to undertake the investigation?
- What are my department's procedures?
- Have I identified a suspect for the crime?



4. INVESTIGATING THE SMUGGLING OF FRAUDULENT MEDICINES.

Once you do this you will need to plan your investigation. You should prepare an investigation plan whether your investigation is reactive or proactive.

Some investigation plans may be very comprehensive, while others may be only 1 page. For all criminal cases your investigation plan should as a minimum include:

- Relevant legislation and offence(s) committed?
- Suspect (if identified)?
- Resources you will need, human, financial and material?
- Does this case have a transnational component?
- Other agencies that may assist you.
- Forensic analysis of the fraudulent medicine.
- Identify relevant investigative methods;
 - Interviews.
 - Surveillance – physical and electronic.
 - Undercover.
 - Technical.
 - Controlled delivery.
 - Informants.
 - Crime Scene.
 - Analytical support

Given the insidious nature of this crime and the potential devastating effects it can have on the community you should utilise the full range of tools at your disposal to investigate the fraudulent smuggling of medicines.

5. SOURCES OF INFORMATION

Information can be gathered from a range of different sources. One of your best sources will be the Pharmaceutical companies that manufacture the original legitimate medications.

However, other sources can generally be divided into 5 categories, these include;

Service Providers

- Freight forwarders
- Transport companies
- Shipping agents
- Doctors
- Chemists



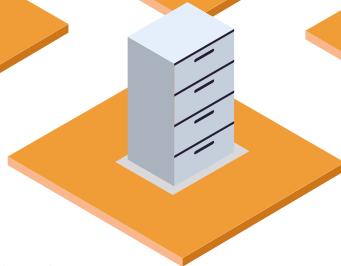
Workers and General Public

- Fishermen
- Street vendors
- Taxi/Uber drivers



Open Source

- TV/Radio
- Print media
- Internet
- Social media



Official Sources

- Officers from your agency
- Other government agencies
- International agencies
- Neighboring Border Liaison Offices



Criminal Sources

- Informants
- Suspects

6. THE INTERNET AND FRAUDULENT MEDICINES

The internet has revolutionised the way we live. As technology has developed so too has the way that criminals use this technology to facilitate their illegal activities. The advent of web-based encrypted communication applications, email, internet banking and the increased sophistication of mobile telephones have provided criminals with greater flexibility, security and reach.

The smuggling of fraudulent medicines facilitated via the internet is a major issue for law enforcement and health departments with an estimated 50% of all medicines sold on the internet being fraudulent. Fraudulent erectile dysfunction medication (Viagra and Cialis) are particularly prevalent and are often sold through links on internet porn sites. There are also many websites selling discounted medicines which are actually fraudulent on the internet. As quickly as these websites are shut down by law enforcement agencies others spring up in their place.

Often these websites are run by organised crime groups but terrorists' groups such as Al Qaeda and Hezbollah have also been known to offer fraudulent medicines. Often ancillary crimes such as money laundering and fraud are directly linked to the online supply of fraudulent medicines.

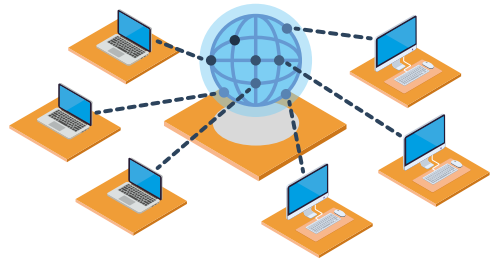
In addition, the criminals running these websites or selling these fraudulent medicines will often communicate between themselves and prospective clients using encrypted web-based platforms including:

- Facebook.
- Line.
- WeChat.
- WhatsApp.
- Messenger.
- Snapchat.
- Telegraph.
- Instagram.
- Alibaba.
- Zalo.

6. THE INTERNET AND FRAUDULENT MEDICINES

While these platforms make it easier for criminals to commit crime, they also present opportunities for investigators. You can use them as possible entry points for undercover investigators and for collecting intelligence and potentially evidence. Never use your own account to communicate with suspects on any of these sites. You should create or utilise covert accounts for your communications.

Should you communicate with suspects on these sites with a view to collecting evidence remember to:



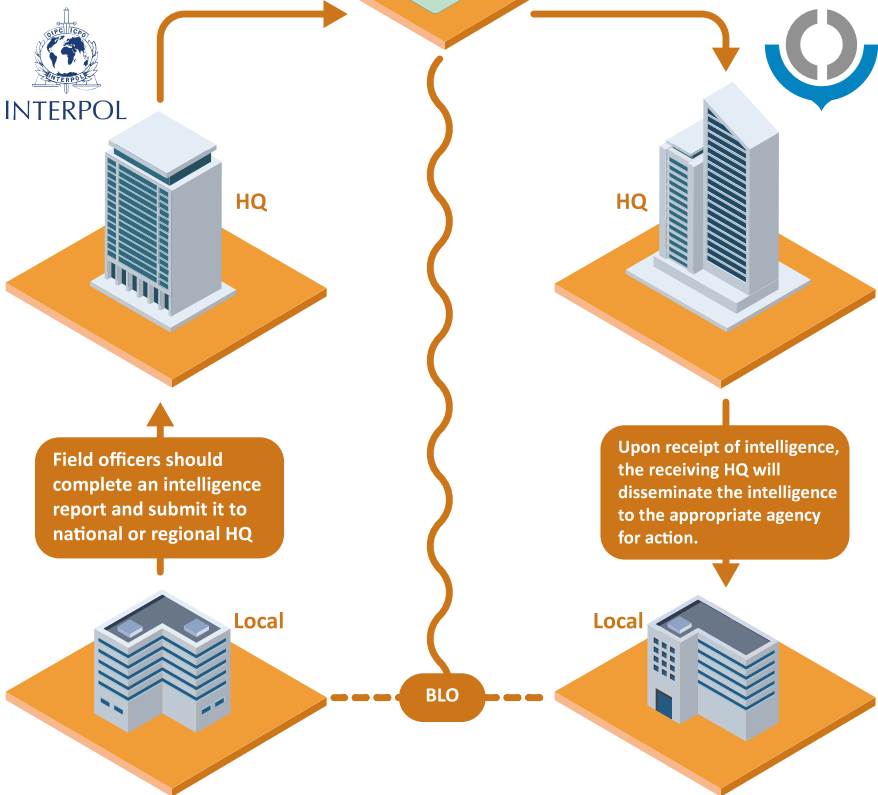
- Ensure that your actions are legal within your jurisdiction.
- Ensure that you have sought the permission from your supervisor.
- **Always use a covert account.**
- Screenshot the suspects profile – this can be changed by them at a later date.
- Screenshot any messages between you and the suspects.
- Record any videos or messages they send to you.
- Always ask for proof of possession – ask for a video with your covert name and the date.
- Do not share your photograph with a suspect.
- Refrain from talking via video with the suspect.
- **It is imperative that you know the market cost of fraudulent medicines if you are to act in an undercover capacity.**

7. SHARING INTELLIGENCE

If the intelligence you have collected may assist a foreign law enforcement agency, then it should be forwarded to your national intelligence unit, World Customs Organisation liaison or Interpol NCB for dissemination.

The intelligence unit should consider sending such intelligence through foreign liaison officers, or international or regional mechanisms (BLO).

The forwarding agency can search for and enter information into international databases and issue notices and alerts.



In addition to the systems above, some countries use mechanisms such as border liaison offices (BLOs) to assist with exchanging information directly.

8. RISK PROFILING

You may encounter the smuggling of fraudulent medicines under many different circumstances. You may find them in or on:

- Containers.
- Trucks.
- Vehicles.
- Vessels.
- Aircraft.
- Mail.
- People.
- Premises.



Now consider how many containers enter and leave your country every year? How many passengers fly into or out of your airports or how many trucks cross your border? Trying to find fraudulent medicines or other contraband amongst all of these circumstances is very difficult without some way to narrow your focus.

To help you identify the potential smuggling of fraudulent medicines it is important that you develop or utilise a risk management system. This system will help you identify shipments or passengers that pose a greater risk of having fraudulent medicines through analysis of risk indicators. Examples of risk indicators include:

- Declared goods are not consistent with type of business of consignee/consignor
- High shipping costs for declared low value consignment (shipment is not economically viable)
- Shipment is a heavier (or lighter) weight than is normal for the declared goods
- Description of goods on the shipping documents does not match Harmonized Systems (HS) code (e.g. using HS code with lower rate of customs import duty)
- Declared goods are known to be used as cover materials for smuggled goods (e.g. scrap plastic, tea, coffee beans, fish, handicrafts, etc.)
- Incomplete/false company names/addresses
- Fraudulent use of genuine company details
- P.O Box or hotel/ suite/ apartment address is listed
- Mobile phone number listed as contact point
- Loading/destination ports used should be consistent with consignor/consignee address
- Importer/exporter is recently established
- First time importing/ exporting
- Check for any known adverse compliance history (of any parties involved – importer, exporter, transporter, logging company)
- Intelligence

This list is not exhaustive; however it represents a good starting point. If you detect one or more of these risk indicators you should consider undertaking an inspection or search.

9. IDENTIFICATION OF FRAUDULENT MEDICATION

Fraudulent medications are by their very nature designed to represent the original and to the inexperienced will look like the same thing.

However, there are several tell-tale signs that you can use to identify if a medicine appears to be fraudulent. These include:

Visual inspection;

- Of the package.
 - Check print quality.
 - Check if the security seal has been tampered with.
 - Check if the hologram has been broken.
 - Check the packaging for UV security features.
 - Check for misspelled words.
 - Check the quality of the packaging.
 - Check that the batch number, expiry date and manufacturer's address are the same on the primary and secondary packaging.
 - Check if the country registration or trace number is properly printed.
- Of the dosage blisters.
 - Check for spelling mistakes.
 - Check for cracks and chips in the medicine.
 - Excessive powder and/or pieces of tablets at the bottom of the blister.
 - Hardening or softening, cracking, swelling, molting, discolouration of the capsule shell.

The price.

- Fraudulent medicines may be cheaper than the original.

Source.

- The source of the medicines is also important. Is it logical for these medicines to be manufactured in the country of origin? If in doubt do some research.
- You should research what medicines are lawfully manufactured in your country and that of your neighbor.
- Is the manufacturers address traceable? Does it contain the exact address of manufacture of just the country name?

RFID tags.

- Does the RFID tag on the packaging match the drugs?
 - You can scan these RFID's using a bar scanner on your phone.

Covert Security Features.

- If in doubt contact the pharmaceutical company who makes the medicines to determine if there are covert security features on the packaging.

Given the vast quantities of original and generic medicines available on the market and the different security features that may be present the best course of action is to contact the pharmaceutical company and/or subject the seizure to forensic analysis.

You may need to do this to ensure a successful conviction. Confer with your prosecutor in relation to forensic analysis.

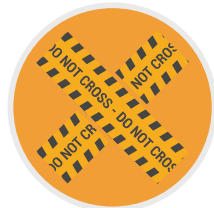
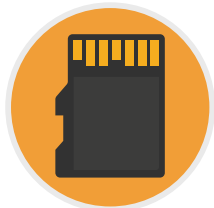
Here are several links to major pharmaceutical companies that may help you in the identification of their products:

- <https://www.sanofi.com>
- <https://www.jnj.com>
- <https://www.merck.com>
- <https://www.novartis.com>
- <https://www.abbvie.com>
- <https://www.gilead.com>
- <https://www.gsk.com>
- <https://www.amgen.com>
- <https://www.pfizer.com>
- <https://www.roche.com>

10. THE SEARCH KIT

Once you have identified that you need to conduct a search for fraudulent medicines ensure that you have the following items at hand to undertake the search (if available):

- Video and still camera with a tripod.
- Storage cards (SD).
- External batteries and cables.
- Evidence bags.
- Exhibit item numbers (can be handwritten).
- Rubber gloves.
- Stationary (pens, notebook, markers).
- Evidence Continuity Forms.
- Crime Scene Tape.
- Protective clothing.
- Bolt cutters.
- UV light.
- Magnifying glass.
- Drug bags.



You will use some or all these items when searching for and documenting fraudulent medicines. It is better to be prepared and have them readily available in a search kit.

You may also be required to seize large quantities of fraudulent medicines contained in shipping containers or on trucks. You will need to take this into account in your planning.

You should only search for and seize fraudulent medicines if you are lawfully entitled to do so.

There are many ways that evidence relating to the smuggling of fraudulent medicines may come into your possession. It may be as a result of a person search, vehicle or vessel search, searching baggage, a container or searching a residential or business premises. Irrespective of how this evidence comes into your possession **you must document the scene and record the actions you take when you seize the digital media device or other supporting evidence.**

This evidence may consist of fraudulent medicines but also evidence that helps prove this trafficking. This may include:

- Cell phones.
- Cargo manifests.
- Computers.
- Bank statements.
- Travel documentation.
- Accommodation documentation.
- Cash.
- Transporter documentation.
- Digital media devices.



11. SECURING THE EVIDENCE

Prior to the search you should:

- Photograph and/or video the search area.
- Draw a map of the scene.
- If you have other officers to assist you assign each a specific role i.e. search, exhibit officer, officer in charge and photographer.

During the search you should:

- Search the area systematically.
- Video the search.
- Document the location where each item is found.
- Bag or secure items seized clearly labelling each with a unique identification number.
- Create a record of all items seized.
- Complete chain of custody documentation.



The packaging and boxes that contain fraudulent medicines may also contain traces of DNA and fingerprints. You should enquire with your Supervisor whether your agency have the facilities to collect and analyse this type of evidence. It may be crucial evidence in identifying suspects where the fraudulent medicines were sourced.

Chain of Custody refers to the chronological documentation and/or paper trail showing the seizure, custody, control, transfer, analysis and disposition of evidence. Because evidence can be used in court to convict someone of a crime, it must be handled in a careful manner to avoid allegations of tampering or misconduct which can potentially compromise a case.

You are responsible for making a record of any fraudulent medicines that comes into your possession and what you subsequently do with that evidence. If you hand it to another officer, or to an expert, or even back to the suspect you must make a record of this movement on a Chain of Custody form.

There are many examples of Chain of Custody forms available on the internet, but you should first check whether your Department has its own form before using one of these.

A chain of custody form should as a minimum include the following information about the evidence you have seized:

- Date Collected.
- Time Collected.
- Item Number or Barcode Number.
- Case or Event Number.
- Who collected the item.
- Where the item was collected.
- The suspects name.
- A through description of the item.
- Offence for which the item was collected.
- Where the item is stored.
- Any person who came into possession of the item, the reason for this, and the date and time that this occurred.



13. CONTROLLED DELIVERIES

Seizure is not the only option available to you when you discover a shipment of fraudulent medicines. Often, the person who is detected in possession of the fraudulent medicines is not the person who is making the most from the crime. Controlled deliveries are a useful technique allowing you to monitor the movement of illicit goods, and may help to identify the destination of contraband, and the main people involved in trafficking.

Consider these steps when planning a controlled delivery:

- Have you confirmed that the medicines are fraudulent?
- Do you have the appropriate authority to conduct the controlled delivery?
- Do you have cooperation from national and international counterparts?
- Is there sufficient time to launch an operation?
- Be careful not to disturb the goods arousing suspicion.
- Replace some of the contraband with substitutes.
- Where possible use a tracking device.
- Where possible use an integrated listening device/video camera to record the opening of the packages by the suspect.

When interviewing suspects:

- Have two officers present.
- One officer should take notes.
- Record the interview wherever possible.
- Consider the welfare needs of the suspect.
- Ensure that female suspects are protected and that they feel safe.
- Consider the need for an interpreter.
- If the suspect is a juvenile, consider the need for a social worker or other authorised support person.

Ask open ended questions, who, what, why, where, when and how to get the suspects version

Sample Interview Questions:

Questioning suspects involved in the smuggling or transport of fraudulent medicines:

- What kind of medicine is this supposed to be?
- How much are you transporting?
- Where did you load it/receive it?
- Who was present when you loaded it/received it?
- Who owns these materials?
- Where are you transporting it?
- Who do you work for?
- How long have you worked for them?
- How much were you paid to transport this? Where is the documentation for this?
- How often do you transport fraudulent medicine?

14. INTERVIEWING SUSPECTS

Questions for suspects engaged in the manufacture of fraudulent medicines.

- What is your name, date of birth, address, phone number and identification number?
- Who owns these premises?
- What is your primary business here?
- What is the name of your business?
- Is your business registered?
- How long has it been registered?
- Do you use the service of an accountant?
- What is his/her name?
- How much income do you generate annually?
- Where do you keep your company records?
- What major assets do you own? [House, car, savings, investments, other business]



- Are you a doctor?
- Are you a chemist?
- How many employees do you have here in the factory?
- How many salespeople do you have?
- Are any of your staff qualified chemists/doctors?
- What medicines are you manufacturing here?
- Are these medicines authentic?
- How can you verify that these medicines are authentic?
- Do you have any written authorisation to manufacture medicines in this factory?
- Who are you manufacturing medicines for?
- How long have you been manufacturing medicines here?
- Who do you sell your medicines too?
- How do you sell them?
- How do you advertise them?
- How do you transport them?
- Where did you source your ingredients?
- Where did you source your pill press?
- Where did you source your laboratory equipment?
- Where do you receive the blister packs for the medicines?
- Who provides your printed boxes/containers?
- Where do you file your documentation?

Try to build up a complete picture of the person's involvement in the crime and their associates.v

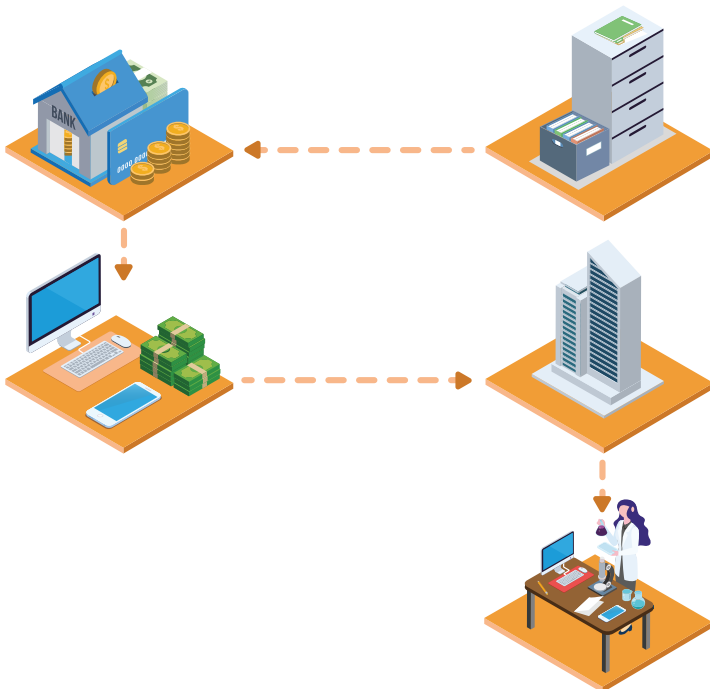
15. FINANCIAL INVESTIGATIONS

Suspects involved in the transnational organised smuggling of fraudulent medicines are engaged in criminal activity that requires the transfer of large sums of money to pay for chemicals used in the production of fraudulent medicines, their transportation and distribution. In some instances, this will be many millions of dollars. Always ensure that you consider a parallel financial investigation for money laundering. These types of investigations can help you identify those profiting most from the crime.

Steps that you can take to collect evidence of money laundering can occur at different times within your investigation. These include:

Suspect Profiling:

- Obtaining court orders or warrants for examination of financial records, including bank records, phone records and tax returns
- Using services of a forensic accountant to examine financial records
- Conducting business and property checks



When conducting surveillance:

- What banks do they use?
- What credit cards do they use?
- What vehicles do they use?
- What properties are they in control of?

When searching a crime scene, look for:

- Mobile telephones
- Bank documents
- Property documents
- Business records
- Financial records
- Computers
- Cash
- Receipt books
- Invoices
- Passports
- Digital recording devices

When interviewing a suspect:

- What is their income and expenses?
- What properties and assets do they own or lease and how they were funded?
- What businesses or companies do they own?
- Who do they work for?
- What bank accounts do they have in your country or overseas
- Who is their accountant

Also consider:

- Conducting forensic examination of digital devices



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