Q: What is the problem with the current definition?
A: A WHO definition exists. But:

- WHO definition does not allow effective prosecution of counterfeiters when used in legislations at the country level; and,
- politically, various countries would like to explicitly exclude sub standards and GMP issues, unauthorized medicines, generics, and IP violations.
- politically, various countries are concerned by the use of the word “counterfeit” due to inherent link to Intellectual Property

The IMPACT developed a new definition dealing with issues of concern, but it does not replace the existing WHO definition.
Q: What are the key elements behind any definition of counterfeit medicine?

A: There are various elements at play

- The key element in counterfeiting is the **false or fraudulent misrepresentation of a medicine’s identity and/or source, with disregard for potential risk to patient safety.**
- Counterfeiting is **linked to trademark infringement**, not patent violations.
- **Counterfeiting is not a quality issue alone. It is a criminal activity.** Intent is a fundamental element of counterfeiting. On the other hand, Counterfeits are distinct from substandard medicines.
- A definition that takes into account these various elements and prompts a framework of commensurate sanctions is appropriate.
- It will need to be adapted to local conditions, including language and legal systems.
- For the purposes of local legislation IFPMA recommends the IMPACT definition.
Q: Will the fight against counterfeit medicines undermine the availability of legitimate generics?

A: No. Our message:

- Measures adopted to combat counterfeits are aimed at products that have never been approved by a national authority, have been manufactured evading regulatory controls by manufacturers who want to remain unknown, and/or have been traded by individuals who deliberately or by negligence contribute to hiding their true origin.

- All these situations are **not related** to the trade of legitimate, authorized, generic medicines by legitimate, authorized generic manufacturers.
Q: Can illegal, unauthorized and substandard medicines be considered counterfeits?

A: No, and here is why:

- An unregistered or unauthorized medicine (originator or generic, produced by the local industry or by multinationals) may not be compliant with national rules, including GMP, but would not be deemed to be a counterfeit unless the operator supplying the product is misrepresenting its identity or source, intending to pass it off as another (approved and legitimate product).

- Counterfeit medicines should also be distinguished clearly from medicines (originator or generic, produced by the local industry or by multinationals) which are sub-standard or out of compliance with GMP quality requirements in the country of intended use. Generally, all counterfeits qualify as sub-standards, but not all sub-standards qualify as counterfeits.

- Counterfeit medicines are one specific type of unapproved/illega medicines that are manufactured evading regulatory controls. It is impossible to measure counterfeit medicines' compliance with established regulatory requirements, including GMP.
Q: Is combating counterfeit medicines part of a global agenda to enforce IP rights, and in particular, patents?

A: No. False representation of “identity and/or source” is in practice linked to trademark infringement, not to patent violations.

✓ In the absence of legal tools specifically addressing counterfeiting of medicines, existing trademark protection rules serve an important vehicle for effective prosecution.

✓ However, given the potential health consequences to patients, which go beyond IP-damage to brand owners, counterfeiting of medicines needs special attention. In many countries existing legal tools used to protect trademarks are not sufficient to deal with the potential health hazard posed by counterfeit medicines. Commensurate sanctions need to be in place.
Q: Is it true that enforcement authorities (police, customs) have no role to play in combating counterfeit medicines, only Drug Regulatory Authorities should be involved?

A: Counterfeiting is a crime, it requires involvement of enforcement

- Experience shows that neither actor alone (DRA, police, private sector) can deal effectively with counterfeits, collaboration is needed.
- It is the role DRAs locally, and of the WHO at the international level, to safeguard public health. This includes protecting patients from the harmful effects of counterfeits.
- Countries should be urged to put in place and enforce a regulatory system which authorizes every medicine in their market, whether manufactured locally or imported.
Q&A: Role of the World Health Organization vs. Role of Interpol

Q: Is collaboration between the WHO and Interpol needed?

A: Yes. The criminal nature of counterfeit medical products requires close collaboration between Drug Regulators and Enforcement Authorities. The interaction between the WHO and Interpol is a parallel of this need, at the global scale.

✓ WHO’s role is to support its members in building capacity to assure quality, safety and efficacy of medicines and to protect patients.

✓ Interpol provides for coordination of enforcement activities in countries, involving both regulators and police/customs, as well as training on the specificities of the health aspects of counterfeit medicines.

✓ Interpol has created an independent unit specifically designed to support the IMPACT Secretariat and the WHO.
Q&A: Technology Responses to Counterfeiting

Q: Can anti-counterfeiting technologies be “the solution” to counterfeiting?

A: Technology should not be **oversold**. Developing countries need to prioritize regulatory and legislative structure capacity and enforcement

- Many common technologies can be defeated
- There is **no** such thing as a “worldwide” applicable **technology**
- Tried and tested technologies are preferred
- IFPMA’s view: **standardization of Identification**, versus **flexibility** for manufacturers to choose **Authentication** features
  - Efpià pilot in Sweden has proved successful: 2-D barcode
“A medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source. The term counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with wrong ingredients; without active ingredient; with incorrect quantity of active ingredient; or, with fake packaging”

WHO Guidelines for the Development of measures to combat counterfeit medicines, 1999
The term counterfeit medical product describes a product with a false representation (1) of its identity (2) and/or source (3). This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components (4), with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging. Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches of or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting

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Notes:
(1) Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behaviour shall be considered during the legal procedures for the purposes of sanctions imposed
(2) This includes any misleading statement with respect to name, composition, strength, or other elements
(3) This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution
(4) This refers to all components of a medical product
For further information, contact the IFPMA

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