

PRELIMINARY DRAFT SURVEY ON NATIONAL LEGISLATION ON "COUNTERFEIT MEDICINES"

Feedback from Member States to the Circular Letter CL 25.2009

The responses received from Member States to the Circular Letter have been reviewed in accordance with the following:

- Step 1. Collation of comments
- Step 2. Translation of responses into English
- Step 3. Screening of answers to identify feedback on:
 - national legislative issues
 - comments to IMPACT document
 - IMPACT definition
 - additional points raised
- Step 4. Legal review of the use of terms and related national legislations
- Step 5. Second independent review from health/medicines regulatory perspective
- Step 6. Consolidation of both reviews into a comprehensive analysis
- Step 7. Validation of information (final checks against original responses)
- Step 8. Finalization of survey review
- Step 9. Publication on the WHO web site
- Step 10. Feedback to the WHO Expert Committee on Specifications for Pharmaceutical Preparations (October 2010)

The attached document is posted for feedback from Member States in case any of their responses might have been misinterpreted or might wrongly reflect their statement. This will be part of the WHO Secretariat validation process (i.e. Step 7 of the process outlined above).

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INTRODUCTION

Antecedents

From the early 1980s, World Health Organization Member States reported cases on counterfeit, spurious, substandard and presumably falsified medicines entering their markets.

In response to reports of Member States on such medicines the World Health Assembly, in its Resolution WHO 41.16, requested WHO to initiate programmes for the prevention and detection of spurious, counterfeited and substandard pharmaceutical preparations in May 1988. The first international meeting on "counterfeit drugs" was organized by WHO in 1992. One of the outcomes of this meeting was the first WHO definition of "counterfeit drug". In May 1994 Resolution WHA 47.13 requested WHO to assist Member States in their efforts in combating the use of counterfeit drugs. In answer to this request WHO initiated the *Project on Counterfeit Drugs*.

In addition, several International Conferences of Drug Regulatory Authorities (ICDRAs) dealt with this issue. The ICDRA held in 2004 in Madrid, Spain, recommended WHO to initiate an international convention on counterfeit medicines. This recommendation was converted into the establishment of the *International Medical Products Anti-Counterfeiting Taskforce* (IMPACT) at a meeting in July 2006 in Rome. IMPACT, in its third General Meeting held in 2008 in Hammamet, Tunisia, developed a more comprehensive definition of counterfeit medicines.

The WHO survey

In November 2009 the Director-General of WHO issued Circular Letter CL 25.2009, which invited Member States to provide information regarding their use of the term "counterfeit medicines" (or equivalents) in national legislation and to provide comments on the newly proposed IMPACT definition.

Sixty Member States responded to the Circular Letter¹. Among them three provided no formal definition and/or specific feedback on the IMPACT document, while 57 mixed responses comprised information on national legislation and terminology, opinions on the IMPACT document and on other issues. Moreover, the corresponding definitions of an additional 13 Member States were collected from published, reliable sources. Thus, 70 definitions were screened in two independent steps, according to their content and the issues raised by the Circular Letter. Firstly, a legal analysis was carried out on the use of terms and related national legislation and how these affected the opinion on the IMPACT definition. Secondly, an independent analysis from a health-care/medicines regulatory perspective was performed.

¹ At the time of preparation of this document responses continue to be received.

Sources of legislation where the term "counterfeit medicine" or equivalent is defined

It should be noted that only about the half of the responding Member States also identified the source of law in question; the statistics are as follows. The majority of Member States, i.e. 65%, defined this term in the Drug Act (or Medicines Act, Health Product Act, etc.); 15% in an act which was not specified; 10% in the Criminal Code; 5% in the Intellectual Property Act; while 5% applied to other decrees.

Definitions of "counterfeit medicine" in the legislation of WHO Member States (and including comments to the IMPACT definition)

The definitions of Member States were classified as follows:

- 31% had no legal definition of "counterfeit medicine"
- 4% used this term exclusively to describe intellectual property/trademark violations. (It should be noted that intellectual property/trademark violation as a non-exclusive qualifier also appeared in other definitions, while the Russian Federation provided two legal definitions originating from two separate legislations. One used the term to describe intellectual property violation, while the other was very close to the IMPACT meaning.)
- Among the remaining 65%, 17% used an intentional definition, while 48% used an enumerative type of definition.

In a further presentation of the data, the total number of the 45 above-mentioned Member States that have defined counterfeit (in the meaning of falsified) medicines in their legislation is taken as 100%.

The term "counterfeit" (or the national equivalent) was used by the majority (more than 70%) of Member States. Several responders (as a rule, not English-speaking Member States) preferred to use the term "falsified", while "illicit", "illegal", "unregistered", "unauthorized", "spurious" and "adulterated" were also reported.

In the European Union the term "counterfeit good" was already used in terms of trademarks and copyrights. The ASEAN definition, by contrast, was nearly identical to the IMPACT one.

The "genus", i.e. the wider category of the intentional (part of) definitions, was "drug/medicine" in 78%, "products/goods" (i.e. permitting the possibility to use the definition for other kinds of goods) in 22%, while only 4% also extended the definition to active ingredients. (As for the latter, it should be noted that in several legislations "drug/medicine" refers to both the preparation and the substance.)

As for the terms "intentionally/deliberately" and "fraudulently/falsely" it is interesting to note that, in spite of international debates on the feasibility (from the law-enforcement point of view) of their inclusion in the definition, 16% of Member States that defined "counterfeit medicine" in their legislation used the qualification relating to the *intention*, 13% described *fraud*, while 29% used both.

Among the further conditions (qualifiers), those related to the IMPACT definition (such as wrong ingredients, packaging, manufacturing source, without active ingredients or with an incorrect amount of active ingredients, in both branded and generic medicines) were used by the great majority of WHO Member States. More than 80% used one or more of the

characteristics originating or deductible from the IMPACT definition. The second group of qualifiers related to intellectual property/trademark rights. Several Member States also used quality, GMP-related (such as production or packaging by unauthorized person, substandard, deteriorated) or other medicines regulatory issue-related (e.g. not registered, wrong indication or expiry date, misleading advertisement) qualifiers in the national definition of counterfeit medicines.

The existing variety of definitions can be explained and understood from four different reasons. The *first* is the influence of the local language that prefers or rejects the local analogue of "counterfeit". The *second* issue is the pre-existing local legal terminology.

Thirdly, in order to avoid room for different interpretation, law-makers sometimes deviate from etymological (*definiendum plus definiens*) definitions. In doing so, they approach the term from the law enforcement point of view, e.g. if the deliberation on counterfeiting is etymologically true, it may be very complicated to prove during prosecution. What is easy to prove is the result (i.e. the product is substandard) even if the latter could be caused by other activities than counterfeiting. *Fourthly*, law-makers may deliberately apply "legal fiction", i.e. extending the meaning of a criminal category to cover as many illegal activities as possible in order to handle the latter by the Criminal Code. This also makes law enforcement easier.

Comments of Member States on the IMPACT definition

Two-thirds of the responders to this question supported the IMPACT definition (although mostly with further comments) while one-third rejected it. The comments recommended, among others, application of other international definitions (such as issued by the Pan American Network for Drug Regulatory Harmonization (PANDRH)), substitution of "counterfeit" with "falsified", extension to cover other health-care products and omission of "deliberation" for the reason explained above. It is interesting to note that opponents to the IMPACT definition opposed more its nomenclature than its content. The main reason has also been discussed above: the opponents had been using the term "counterfeit" for the infringement of intellectual property rights. One Member State replied that the definition was not necessary at all.

STUDIES ON THE DEFINITION OF "COUNTERFEIT MEDICINES" IN WHO MEMBER STATES

The aim of this study, as requested by WHO, was to compare and analyse the definitions of "Counterfeit medicines" given by WHO Member States in reply to the WHO questionnaire.

In addition, definitions provided by other Member States in reliable, published legal sources, were taken into account.

The method comprised an assessment of the definitions provided by WHO Member States to a WHO request and compares them to former and present WHO definitions.

Contents

1. Terms used in this study for different definition types (also referred to below)
2. Types of definition used by WHO Member States
 - 2.1 No *expressis verbis* definition (in the WHO meaning)
 - 2.2 (Rather) Intentional definition
 - 2.3 (Rather) Enumerative definition
3. Detailed analysis of the definitions
 - 3.1 The "wider" categories used in intentional definitions (or intentional parts of the definitions)
 - 3.2 Main qualifications used in intentional definitions (or such parts of the definitions)
 - 3.3 The lists (characteristics) in enumerative definitions
 - 3.3.1 Types of the characteristics
 - 3.3.2 Presentation of the characteristics in order of frequency
 - 3.3.3 Frequency of use of the different qualifiers/characteristics according to their origin and/or possible cause
4. Assessment of the definitions of "counterfeit medicines" (or equivalent) in the Member States
 - 4.1 Language and pre-existing legislative terms
 - 4.2 The nature of legal definitions: the unambiguity requirement
 - 4.3 Application of "legal fiction" to involve as many illegal activities around medicines into the same crime category
5. Summary

1. Terms used in this study for different definition types (also referred to below)

- *Intentional definition* (genus and the necessary and sufficient conditions): "Counterfeit medicines" are [genus = wider category] that [qualification of the necessary and sufficient conditions].
- *Enumerative definition*: a list [of different types] with or without an intentional definition.

For the sake of completeness, it should be noted that there is also a third kind of definition, sometimes used in legal texts, namely:

- *Diminutive definition*: any of those before plus: "[Definition or list] are not counterfeit medicines". However, this type of definition has not been applied for counterfeit medicines in the Member States while the IMPACT² definition uses its elements.

Notes

- Existing national definitions have been analysed exclusively (i.e. no planned ones, except when a bill has already been issued, or there have been proposals to or opinion of the IMPACT definition).
- Naturally, there is a thin line between an intentional definition with many conditions/qualifications and an enumerative definition. As a rule, one-sentence definitions have been classified as intentional.
- Terms such as:
 - "medicine" and "drug" and "pharmaceutical" (product) or, e.g. "therapeutic goods"
 - "falsified" and "counterfeit" (see the remark in 3.3)
 - "deliberately" and "intentionally"
 - "ingredients" and "composition"
 - "manufacturer" and "producer"
 - "adulteration" and "wrong ingredients"were *not* taken as being different.

2. Types of definition used by WHO Member States

2.1 No *expressis verbis* definition (in the WHO meaning): Austria, Belgium (only mention "falsified or imitated" ones without defining them), Brazil ("falsified" is only mentioned while "counterfeit" is linked to intellectual property rights), Burundi, Cameroon, Czech Republic, Estonia, France, Honduras, Hungary, Iraq, Malta, Mexico, New Zealand, Peru (although the 1992 WHO definition is used in administrative activities), Poland, Senegal, Serbia, Suriname, Sweden, Switzerland, Turkey.

This means that, to date, no *expressis verbis* legal definition of "counterfeit (or falsified, etc.) medicines" exists in at least 22 WHO Member States. Moreover, it should be noted that this term does exist but is used to describe trademark/general Intellectual Property (IP) rights' violation exclusively in a further three Member States: Japan, Morocco and South Africa. The Russian Federation provided two different legal definitions originating from two different types of legislation. One of them used the term "counterfeit" to describe IP violations while the meaning of the other was close to that of the WHO definition. Moreover, the IP violation meaning is used exclusively in the Community Law of the European Union. (In the EU countries medicine falsification is covered by another or no term, see below.) This

² Definitions. IMPACT Principles and Elements for National Legislation against Counterfeit Medical Products. Text endorsed by IMPACT General Meeting (12 December 2007) and in the third General Meeting, Hammamet, Tunisia in 2008.

purely IP-interpretation was *not taken into account* in the analysis below (unless definitions include the IP or trademark violation, see later).

2.2 (Rather) Intentional definition: Belarus, El Salvador, Georgia, Germany, Haiti, Indonesia, Lao People's Democratic Republic, Pakistan, Russian Federation, Singapore, Uzbekistan, Venezuela.

The minority: 12 responding WHO Member States used this kind of definition.

2.3 (Rather) Enumerative definition: Argentina, Australia, Botswana, Brunei Darussalam, Cambodia, Chile, People's Republic of China, Colombia, Congo, Costa Rica, Croatia, Ecuador, Egypt, Guatemala (bill), India, Kenya, Latvia, Liberia, Malaysia, Maldives, Moldova, Myanmar, Nicaragua, Niger, Nigeria, Oman, Philippines, South Africa, Thailand, Ukraine, United Republic of Tanzania, United States of America, Viet Nam.

The majority: 33 responding Member States had enumerative definitions for counterfeit medicines.

Note: Naturally, there is no exact borderline between intentional and enumerative definitions. A one-sentence definition with one or two qualifiers could simply be judged as intentional while a list ((a), (b), (c), (d), etc.) is a clear-cut enumerative definition. However, a definition comprising one or two concise sentences with *several* qualifiers is on the borderline. This is the reason why "rather" has been used in order to give some subjective nature to this classification.

3. Detailed analysis of the definitions

3.1 The "wider" categories used in intentional definitions (or intentional parts of the definitions)

- Drug/medicine: Argentina, Australia, Belarus, Brunei Darussalam, Cambodia, Chile, People's Republic of China, Colombia, Congo, Croatia, El Salvador, Germany, Guatemala (bill), Haiti, India, Indonesia, Lao People's Democratic Republic, Latvia, Liberia, Malaysia, Maldives, Moldova, Myanmar, Nicaragua, Niger, Nigeria, Pakistan, Philippines, Russian Federation, Thailand, Ukraine, United Republic of Tanzania, United States of America, Uzbekistan, Venezuela
- Also active ingredient/substance: Germany, Thailand
- Product/goods: Botswana, Costa Rica, Ecuador, Egypt, Georgia, Kenya, Oman, Singapore, South Africa, Viet Nam.

Summary: The majority, i.e. 35 Member States, focus the definition to *medicines* while 10 use it in a more general way to *products*. Only two responding Member States were so specific in the definition to also include *active ingredients*.

In several cases *products* was specified to permit the use of the definition in other (named) product categories.

3.2 Main condition qualifiers used in intentional definitions (or such parts of the definitions)

- Intentionally/deliberately (produced, etc.): Argentina, Australia, Belarus, Botswana, Brunei Darussalam, Cambodia, Georgia, Haiti, Indonesia, Kenya, Latvia, Liberia, Malaysia, Maldives, Moldova, Nicaragua, Oman, Philippines, Ukraine, Viet Nam
- Fraud/fraudulently/falsely: Argentina, Belarus, Botswana, Brunei Darussalam, Croatia, Egypt, El Salvador, Haiti, Latvia, Liberia, Malaysia, Maldives, Moldova, Myanmar, Oman, Philippines, Thailand, Venezuela, Viet Nam.

It is interesting to note that, in spite of the international debates on the feasibility (from the law enforcement point of view, see below) of the inclusion of these terms into the definition, among the answering Member States 26 applied these qualifications somewhere in the definition, namely:

- seven used the qualification relating to the *intention*;
- six described *fraud*; and
- thirteen used both (in the meaning of ""intention to fraud").

3.3 The lists (characteristics) in enumerative definitions

Note: Every categorization is somewhat artificial. In the analysis below the "closest" categories were used as a rule. The list below contains characteristics that were referred to in the definitions.

For the analysis, characteristics of counterfeit medicines or those that might originate from the same root were taken as the same category. The following explanations apply.

- "Product name identical with another product" and "trademark violation" were taken, although uneasily, into the same category. The fact is that the former may happen:
 - as the consequence of counterfeiting, but also
 - without any intention (e.g. there is only a one-letter difference between the names of two existing genuine products and by error: a good manufacturing practice (GMP) defect or a misprinted batch bearing the name of the other product reaches the market.

Only detailed analysis in the original language could reveal the meaning that the given Member State used and possibly someone wished to underline intentionally fraudulent labelling. This explains the "(?)s" in Table 1 below.

- Moreover, the two above explanations could also be covered under the general "incorrect, etc., labelling, packaging" group. When several Member States used both qualifications these were given in a different group.
- The ""wrong expiry date" may equally be a falsified characteristic or a mistake. This is the reason why "wrong indication" was not deducted as a criterion for falsification from the IMPACT definition ("this includes any misleading statement with respect to... or other elements")

- Production or repackaging by an unauthorized person does not necessarily mean falsification. If registered, otherwise "genuine" medicines are produced this way; this violates the law but is not falsification of the medicine.
- The same applies to use in spite of prohibition and wrong advertisements.
- Wrong indication/claim was also taken as being different from falsification. In some parts of the world indications may be patented or data may exclusivity apply to them (e.g. European Union); a wrong indication may not be counterfeiting (in the meaning of deliberate falsification), but patent violation.

3.3.1 Types of characteristics

- Both branded and generic/multisource: Argentina, Brunei Darussalam, Croatia, El Salvador, Latvia, Liberia, Malaysia, Maldives, Moldova, Niger, Oman, Ukraine.
- With correct ingredients: Argentina, Botswana, Brunei Darussalam, Croatia, Ecuador, Latvia, Liberia, Malaysia, Maldives, Moldova, Niger, Oman, Philippines, Ukraine.
- Wrong ingredients: Argentina, Australia, Belarus, Botswana, Brunei Darussalam, Cambodia, Chile, People's Republic of China, Congo, Costa Rica, Croatia, Ecuador, Egypt, Georgia, Germany, Guatemala (bill), India ("spurious"), Latvia, Liberia, Malaysia, Maldives, Moldova, Nicaragua, Niger, Oman, Philippines, Russian Federation, Thailand, Ukraine, United Republic of Tanzania, Uzbekistan, Venezuela, Viet Nam.
- Without active ingredients: Argentina, Australia, Botswana, Brunei Darussalam, Cambodia, Congo, Croatia, Ecuador, Latvia, Liberia, Malaysia, Maldives, Moldova, Niger, Oman, Philippines, Ukraine, Viet Nam.
- Incorrect/lower amounts of active ingredients: Argentina, Australia, Botswana, Brunei Darussalam, People's Republic of China, Congo, Croatia, Ecuador, El Salvador, Guatemala (bill), Latvia, Liberia, Malaysia, Maldives, Moldova, Nicaragua, Niger, Oman, Philippines, Thailand, Ukraine, Viet Nam;
- Wrong quality active ingredients: Cambodia, Congo, Costa Rica, Ecuador, El Salvador.
- Active ingredient source: Congo, Egypt, El Salvador.
- Produced from active ingredients without approval number: People's Republic of China.
- Product size: Australia.
- Fake/false/misleading packaging (including wrong identity or wrong/modified/no label): Argentina, Australia, Botswana, Brunei Darussalam, Cambodia, Chile, People's Republic of China, Colombia, Costa Rica, Croatia, Egypt, Georgia, Guatemala (bill), Indonesia, Kenya, Latvia, Liberia, Malaysia, Maldives, Moldova, Myanmar, Oman, Nicaragua, Nigeria, Pakistan, Philippines, Singapore, Venezuela, Viet Nam.
- Misleading in terms of the product nature: Haiti, Russian Federation, Ukraine.
- Wrong indications/claims: People's Republic of China, Costa Rica, India ("misbranded"), Nigeria, United Republic of Tanzania, Venezuela.
- Wrong expiry date: Myanmar, Thailand, Venezuela.
- Wrong manufacturer/source: Argentina, Australia, Belarus, Botswana, Cambodia, Colombia, Ecuador, Egypt, India ("spurious"), Kenya, Liberia, Malaysia, Maldives, Myanmar, Russian Federation, Thailand, Ukraine, United Republic of Tanzania, United States of America, Uzbekistan, Singapore, Venezuela.

- Name identical to another existing product/trademark or IP right violations: Australia, Chile, Germany, Haiti, India ("spurious"), Kenya, Lao People's Democratic Republic, Latvia, Philippines, Thailand, United Republic of Tanzania, Viet Nam.
- Produced by unauthorized person: Cambodia, People's Republic of China, Colombia, Indonesia, Philippines.
- Marketed/imported without approval or not registered: People's Republic of China, Colombia, El Salvador, Nigeria, Philippines.
- Produced/marketed without testing: People's Republic of China.
- Repackaged by unauthorized person: Cambodia.
- Deteriorated: People's Republic of China.
- Used in spite of its prohibition: People's Republic of China.
- Any related document or record wrong: Australia.
- Advertisement misleading: Australia.
- Product quality differs from the genuine one: Cambodia ("outside defined pharmacopoeial standard"), Ecuador, Philippines (less than 80%), Thailand (more than 20% deviation).
- product efficacy different from the genuine one: Ecuador, Nigeria.

3.3.2 Presentation of the characteristics in the order of their frequency

The characteristics (listed elements), presented in their order of frequency, are compared with the "WHO 1992" and "third IMPACT" ones in Table 1 below.

- "Frequency" means the number of Member States that used it in the definition.
- In the "WHO 1992" and "third IMPACT" columns "+" indicates that the qualification is applied in, or deducible from, these definitions while "—" means the definition excludes it.

Table 1

Frequency	Qualifiers/characteristics	WHO 1992	Third IMPACT
33	wrong ingredients contained	+	+
29	wrong/fake label/packaging	+	+
22	wrong source/manufacturer	+	3
22	incorrect amount of APIs	+	+
18	without any API	+	+
14	correct ingredients (is also possible)	+	+
13	intentionally and fraudulently	+	+
12	both branded and generic	+	+
12	trademark/IP, the product name is identical to another	(?)	(-?)
7	intentionally (alone, fraudulent not mentioned)	(+)	(+)
6	fraudulently (alone, intention not mentioned)	(+)	(+)
6	marketed/imported without approval or not registered		—
6	wrong indication/claim		
5	API quality wrong		—
5	produced by unauthorized person		
4	product quality different from standard		—
3	API source different from claimed		+
3	wrong expiry date		
3	different product nature		
2	trade mark violation		—
2	efficacy different from genuine one		
1	repackaged by unauthorized person		
1	used in spite of its prohibition		—
1	wrong product size		
1	no product testing done		—
1	deteriorated		—
1	any document wrong		+
1	API without approval number used for product		—
1	misleading advertisement		—

The Table shows that the WHO/IMPACT definitions have been widely accepted by Member States.

The issue as to why some Member States applied additional qualification, even those contradictory to the IMPACT explanation, is explained below in part 4.

3.3.3 Frequency of use of the different qualifiers/characteristics according to their origin and/or possible cause

The above qualifying elements are presented below on the basis of their origin (WHO) or content (possible cause). It is stressed that the following comparison does not relate to the full definitions in the Member State but to the individual qualifying elements, in order to show how plausible (generally accepted) it is that such elements should be part of the definition. It is emphasized again that the classification below, like any classification, is subjective.

Those originating with "WHO 1992" definition:

- both branded and generic/multisource
- correct ingredient
- wrong ingredients
- without active ingredients
- incorrect/lower amounts of active ingredients
- fake/false/misleading packaging (incl. wrong identity or wrong/modified/no label)
- wrong manufacturer/source.

Argentina, Australia, Belarus, Botswana, Brunei Darussalam, Cambodia, Chile, People's Republic of China, Congo, Colombia, Costa Rica, Croatia, Ecuador, Egypt, El Salvador, Georgia, Germany, Guatemala (bill), India ("spurious"), Indonesia, Kenya, Latvia, Liberia, Malaysia, Maldives, Moldova, Myanmar, Nicaragua, Niger, Oman, Pakistan, Philippines, Russian Federation, Singapore, Thailand, Ukraine, United Republic of Tanzania, United States of America, Uzbekistan, Venezuela, Viet Nam.

Altogether, 41 Member States used one or more of the characteristics originated or deductible from the "WHO 1992" definition in their national one.

IP rights/trademark violation

- trademark/general IP rights violation
- name identical to another existing product (with the question mark indicated above).

Australia, Chile, Germany, Haïti, India ("spurious"), Kenya, Lao People's Democratic Republic, Latvia, Philippines, Thailand, United Republic of Tanzania, Viet Nam.

Twelve Member States felt it was important enough to be an independent part of the definition. However, as pointed out earlier, the "name identical with another product" is not necessarily used in the meaning of trademark violation.

Violation of national registration, manufacturing and marketing rules:

- produced from active ingredients without approval number
- wrong product size
- wrong expiry date
- produced by unauthorized person
- marketed/imported without approval or not registered
- used in spite of its prohibition
- any related document or record wrong.

Australia, People's Republic of China, Cambodia, Colombia, El Salvador, Indonesia, Myanmar, Nigeria, Philippines, Thailand, Venezuela.

Eleven Member States wanted to identify these issues with counterfeiting, although they may also appear with genuine products.

Violation of advertisement rules:

- advertisement misleading
- wrong product nature indicated
- wrong indications/claims.

Australia, People's Republic of China, Costa Rica, India, Haiti, Nigeria, Russian Federation, Ukraine, United Republic of Tanzania, Venezuela.

One of the outcomes of counterfeiting is that the product advertisement is false. However, it is not inevitably true vice versa. Still, 10 Member States included such a qualifier in the "counterfeit medicine" (or equivalent) definition.

Rather GMP/good distribution practices (GDP) issues than clear-cut counterfeiting (although could be signs of the latter):

- wrong quality active ingredients
- produced/marketed without testing
- deteriorated
- product quality differs from the genuine one (i.e. the approved specification).

Cambodia, People's Republic of China, Congo, Costa Rica, Ecuador, El Salvador, Philippines, Thailand.

Eight Member States felt that these characteristics are direct signs of counterfeiting rather than its outcomes that could be caused by another issue.

Extension of the outcome of one WHO definition element to the active ingredient:

- wrong active ingredient source.

Congo, Egypt, El Salvador.

Three Member States felt it logical and necessary.

Different efficacy:

- product efficacy different from the genuine one (i.e. from the expected one).

Ecuador, Nigeria

These two Member States also used this qualifier. It should be noted, however, that the reason for "different efficacy" can be, besides counterfeiting, GMP/GDP failure (e.g. higher compression pressure in tablet manufacturing resulting in poor disintegration, and dissolution or tablet matrix changes during improper storage).

4. Assessment of the definitions of "counterfeit medicines" (or equivalent) in Member States

[Note from the WHO Secretariat:

This needs to be double-checked with translators and Russian-speaking colleagues as errors have been found in the English translation of the Russian responses. Instead of "counterfeit medicinal substances" "medicinal products" or "preparations" should be read. In Russian most probably лекарственное средство was written. However, this term means medicinal product, not substance. It is also clear, taking into account that the Russian Act speaks about "its false composition": substances, unlike preparations have no composition. It should be corrected]

4.1 Language and pre-existing legislative terms

If such multicultural and multilanguage communities such as those found in WHO Member States are asked about a legal definition, the answers will inevitably mirror the influence of the native languages as well as the already existing legal terminology.

For instance, Chile commented that "medicinal product" in the IMPACT definition (which strictly means "medicine" = "drug" — in the European meaning) is a wrong term, for it(s Spanish analogue) " also means cosmetics, medical devices, etc." The same appears in the French comment: "medicines" and "medical products" have a different meaning. (A similar confusion also appeared in Europe. If the English "medicinal product" is translated into German as "Medizinprodukte", the latter means "different products" while the correct equivalent is "Arzneimittel". Similarly the — more "American English" — "drug" is avoided in the English of the European Union as this would mean "narcotic" in French.)

It has been recognized from the answers which, in some regions, the term "counterfeit" is more or less related (when used as a legal term) to IP right violation. (This explains, e.g. the information from Morocco.) Morocco uses the French term that is equal to "fraudulent" to describe falsified medicines. The European Union also uses "falsified" (and not counterfeit) in the same meaning. The Russian comment also reflected this issue. India uses terms such as "spurious and misbranded".

It means that the question: Do you have a definition for "counterfeit medicinal products" with reference to the IMPACT one, gave rise to answers pointing out that "medicinal products" and "counterfeit" (according to Member States' language and existing legal terms) has other meanings such as "deliberate falsification of products intended for prophylactic, diagnostic or therapeutic use".

As for the IP issue, the interest of some groups to put the IP right violation under the "counterfeit medicines" umbrella should also be recognized.

4.2 The nature of legal definitions: the unambiguity requirement

In order to avoid room for difference in interpretation, law-makers ("codifiers") sometimes deviate from etymological (*definiendum plus definientia*) definitions. In doing so, they approach the term from the law enforcement point of view.

The best example is the definition of "narcotics" in the United Nations Conventions. Narcotics are substances and preparations that induce drowsiness, sleep, stupor, insensibility, etc., and that these effects (and their rate) are complicated to prove, e.g. during litigation. Thus, the legal "definition" of a narcotic is whether or not it is listed on the Schedules of the Convention. If it is on some of the Schedules, it *is* narcotic.

This is also valid to several definitions of counterfeit medicines in some Member States. They are understood as "deliberate fraud to market an imitation of an existing medicine" (unless the language or pre-existing legal definition excludes it, see above). From a purely etymological point of view the deliberative action is self-evident for there are "sins" that simply cannot be committed "by chance" or "carelessly", e.g. defamation and counterfeiting. However, the intention should have been proven in the litigation in this case. It is complicated and sometimes almost impossible. Thus, from the law enforcement point of view, it is better to omit it as the "result" can be proven much easier.

Such "results" that are easy to prove are, among others, production, import or repackaging by an unauthorized person, a wrong expiry date, different efficacy (from the "genuine" product), etc. Medicinal product quality also belongs to this, particularly when the deviation from the requirement is fixed (e.g. in 20%, see the answers from Ecuador, Philippines and Thailand).

4.3 Application of "legal fiction" to involve as many illegal activities around medicines in the same crime category

This happens when the law-maker sweeps all the possible *signs* of medicine falsification into one enforcement category (although these could well be caused by other activities than deliberate fraud, e.g. poor GMP standard). The examples may be "the product not tested", deteriorated, etc. Moreover, law-makers often make use of public fear of a specified illegal activity (such as medicine counterfeiting) to qualify the sinfulness of some activities higher in the Criminal (or Civil) Code. This explains, e.g. appearance of marketing of unregistered products or misleading advertising as medicine counterfeiting.

However, it should be emphasized that this approach is by no means universal. When the intention is to put medicine counterfeiting under the Criminal Code (which is not presently the case in a number of Member States), one should be extremely careful with the elements of its definition. The wider activities are involved in the definition (e.g. clear-cut GMP violations), the less law-makers (of the countries where medicine counterfeiting is still not a crime) would be willing to accept it in the criminal code.

5. Summary

The issues dealt with under item 4 explain the confusion around the definition of "counterfeit medicines", including language and pre-existing terms, the nature of legal definitions and their categorization.

It should also be recognized that already existing national legislations, independently of the reason and intention why they were issued as such, were extremely difficult to change for a global definition.
