

PROPOSAL BY ARMENIA

**Concerns on the interpretation
of the Term “Adulteration”**

Article 5, paragraph 2, of the Council of Europe MEDICRIME Convention (CETS No. 211)

Starting point: what the existing proposal already establishes

The uploaded deck provides the legal anchor and the rationale for action.

Legal anchor

Article 5(2) applies the manufacturing offence framework to adulteration of medicinal products and, as appropriate, medical devices, active substances and excipients.

Interpretative gap

The Convention contains the term “adulteration”, but the term is not defined in the Convention text and only briefly explained in the Explanatory Report.

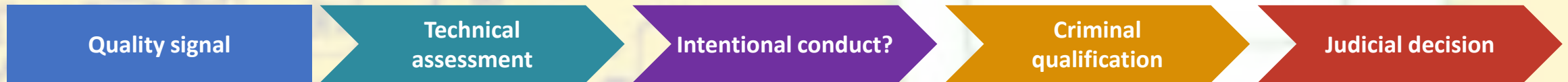
Need for action

A guidance note can support a common understanding and reduce uneven implementation across States Parties.

The next step is to transform a short proposal into a structured concept paper and work programme.

Core logic

The practical problem is not only the word “adulteration”; it is how authorities should recognise and qualify it.



Two opposite risks must be managed at the same time:

Risk A

Ordinary quality defects, GMP deviations or OOS results are over-criminalised without evidence of intentional adulteration.

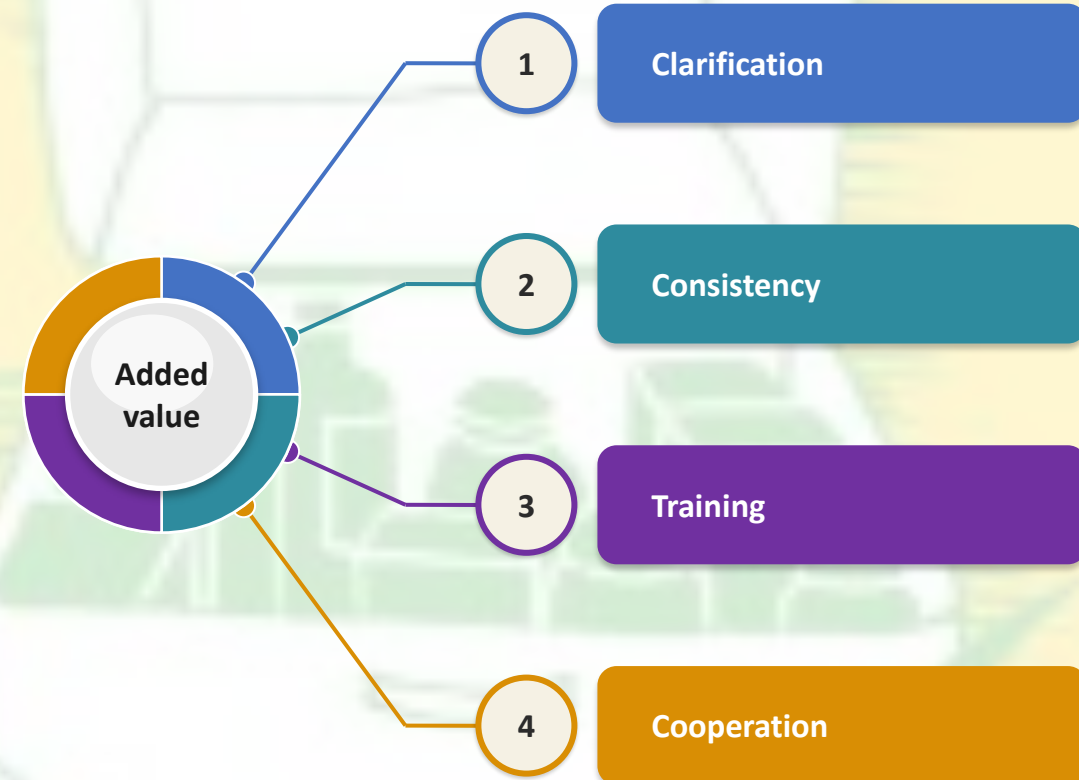
Risk B

Intentional adulteration is missed because it initially appears as a regulatory or quality issue only.

Why a Guidance Note is necessary?

The guidance note should explain not only the meaning of adulteration, but also its added value for implementation.

- Promote legal certainty for criminal justice authorities and competent regulatory bodies.
- Support harmonised implementation of Article 5(2) by States Parties.
- Create a common language for investigators, prosecutors, judges, inspectors and laboratories.
- Support training and case assessment without replacing national criminal law.



Who will use it?

A single guidance note can serve different professional communities.

Judges

A structured explanation of what makes adulteration legally distinct from other product-quality problems.

Prosecutors

A practical framework for assessing whether the evidence supports the criminal offence.

Investigators

Indicators, document trails and cooperation routes for building a coherent case.

Regulators

A shared interface between GMP/market surveillance findings and criminal-law follow-up.

Training use

- Common examples and non-examples
- Case studies based on anonymised scenarios
- Decision trees for escalation from quality finding to criminal investigation
- Terminology that can be translated and used across States Parties

Interpretative anchor

The draft should stay close to the Convention and its Explanatory Report.

Article 5(2)

Applies to adulteration of medicinal products and, as appropriate, medical devices, active substances and excipients.

Explanatory Report

Describes adulteration as making a product poorer in quality by injuriously adding or substituting another undeclared substance.

The Guidance Note should translate this short explanation into practical legal and evidential criteria.

Key boundary: adulteration is not every defect

This distinction will make the guidance legally safe and practically useful.

Quality defect / GMP issue

Deviation, OOS/OOT result, contamination, mix-up or documentation weakness may require regulatory action, recall or CAPA.

Adulteration signal

The product is made poorer in quality through injurious addition or substitution of an undeclared substance.

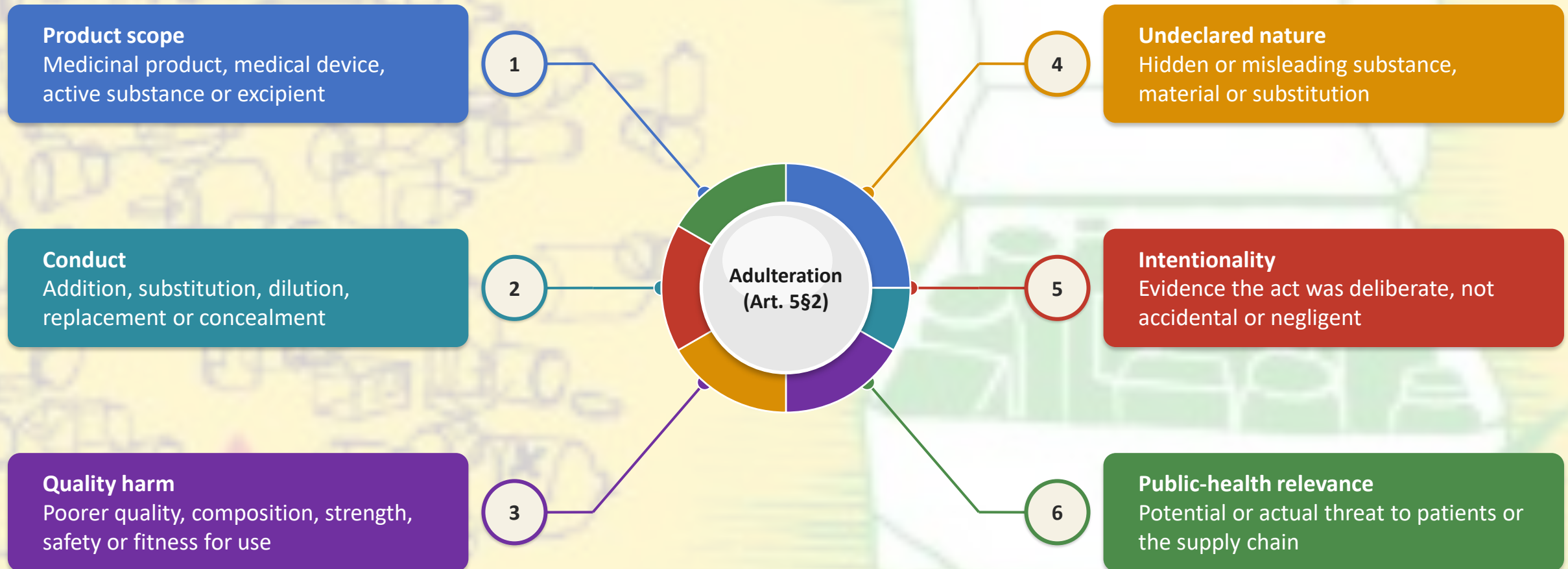
Criminal case

The facts support intentional conduct, relevant product scope, causal/product-quality impact and evidence linking persons or legal entities.

The guidance should protect both sides: avoid unjustified criminalisation and avoid losing serious intentional cases inside purely regulatory processes.

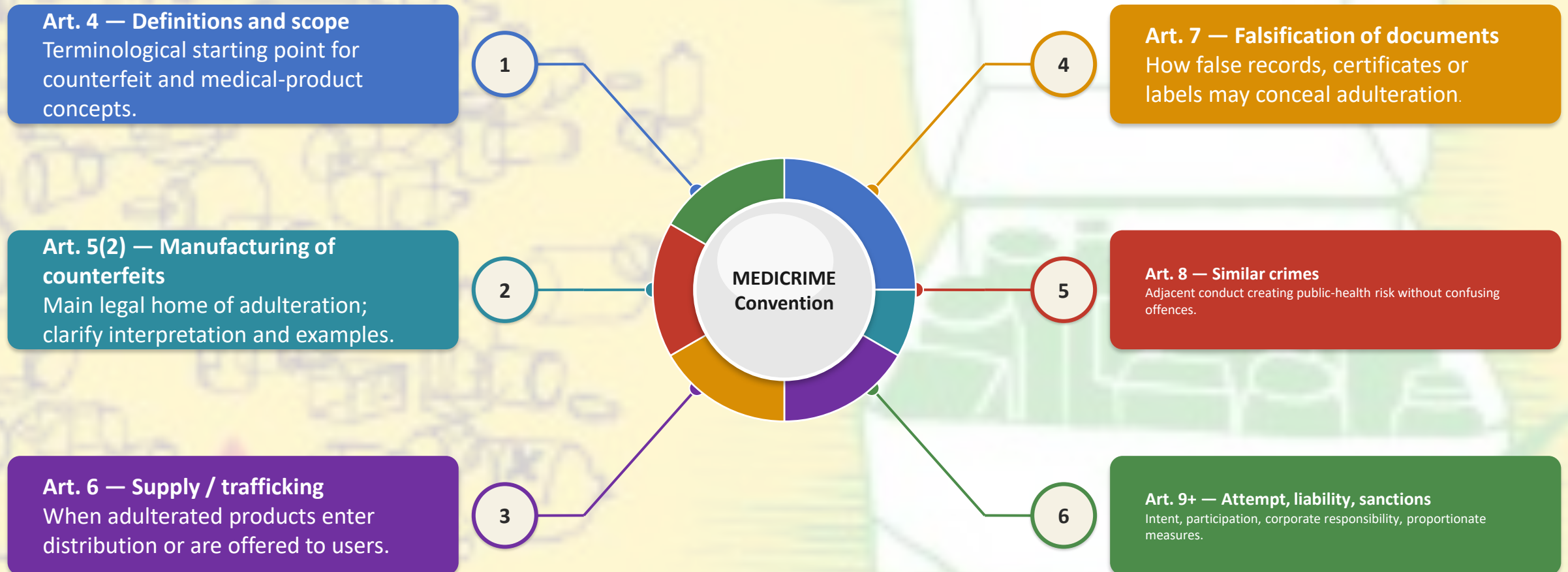
Some elements which may be clarified in the Guidance note

A practical checklist can help authorities ask the right questions early.



Preliminary article-by-article integration map

The concept paper can explain where adulteration fits across the Convention.



Evidence logic for practical application

The guidance can define how regulatory facts become criminally relevant evidence.



Decision path for case assessment

A simple path can be included as an annex or training tool.

1

Is the product within Article 5(2) scope?

2

Is there addition, substitution or comparable manipulation?

3

Is the change undeclared or concealed?

4

Does it make the product poorer in quality or injurious?

5

Is there evidence of intentional conduct?

6

Which offence and procedural pathway is most appropriate?

Result: consistent triage from technical suspicion to legal qualification.

Training and capacity-building value

The guidance note can be designed so it is immediately usable in training programmes.

- Common terminology and plain-language explanation of Article 5(2).
- Examples distinguishing accidental contamination, poor GMP control and intentional adulteration.
- Scenario-based exercises for mixed groups: inspector + investigator + prosecutor + judge.
- Templates for requesting laboratory, manufacturing and supply-chain evidence.

Suggested training package

One core module for all authorities, plus profession-specific annexes for investigators, prosecutors, judges and regulatory authorities.

Practical output

A shared checklist that can be translated and used during real case triage.