European Confederation of
Pharmaceutical Entrepreneurs AISBL

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Public consultation on the

DELEGATED ACT ON THE CRITERIA TO BE CONSIDERED AND THE VERIFICATIONS TO BE MADE WHEN ASSESSING THE POTENTIAL FALSIFIED CHARACTER OF MEDICINAL PRODUCTS INTRODUCED IN THE UNION BUT NOT INTENDED TO BE PLACED ON THE MARKET

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Comments of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE, www.eucope.org) represents via the member associations (the German Pharmaceutical Industry Association (BPI), the Ethical Medicines Industry Group (EMIG) of the UK, the German Biotech association BioDeutschland as well as the Swedish associations of mid-sized innovative companies IML and SwedenBIO), more than 900 mid-sized innovative member companies, many of them SMEs. In addition, many innovative companies from Sweden, UK, France, Bulgaria, Italy, Greece, Germany, the Netherlands and Austria are represented on the board of the association.

EUCOPE supports the European Union and other international initiatives in their fight against counterfeit and falsified medicines. We appreciate the opportunity to comment on the above mentioned concept paper of the European Commission.

Consultation item n°1: please comment on this above-mentioned possibility for checks and verifications (paragraphs 15, 16, 17).

EUCOPE suggests a system whereby checks and verifications are carried out in accordance with a **risk-based approach**. The measures mentioned in paragraphs 15, 16 and 17 are not necessary for every situation.

The delegated act should give guidance for national authorities which criteria indicate an increased possibility of a falsification, such as the integrity of the outer packaging or the compliance of data in the shipping documents with those on the outer packaging (e.g. strength, batch number).

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Consultation item n°2: do you consider that all the verifications mentioned in paragraphs 15, 16 and 17 should be carried out? If not, in which cases would it not be necessary to check all these verifications?

Generally, the **analytical testing** of the composition as well as verifications of the packaging and of the labeling should be a **last option**.

The basis for the checks by the authorities should be the shipping documents. If a control of the shipping documents leaves room for doubt, further information concerning the manufacturers could be requested from the importer or wholesaler of those products.

EUCOPE would like to reiterate that clear guidance for the authorities is crucial to ensure that the “level and range of controls and verifications should be governed by the principle of proportionality to avoid unjustified disruptions of trade flows." (point 18).

Consultation item n°3: please comment on this consultation topic.

EUCOPE fully agrees with the proposal of the Commission that in the delegated act a system should be maintained where checks and verifications are performed by different authorities in the Member States and that these authorities lay down clear procedures for cooperation between themselves (points 20/21).

Consultation item n°4: please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

When drafting the delegated act it is crucial to consider the implications of extensive testing of pharmaceutical products at the European Borders from a Good Storage Practice (GSP) / Good Distribution Practice (GDP) perspective.