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

CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

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Submission by the Irish Medicines Board, the Competent Authority in Ireland for medicinal products, medical devices and cosmetic products, and the Irish Customs Administration, the Competent Authority for Customs in Ireland.

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

1. POSSIBLE CHECKS AND VERIFICATIONS

The checks and verifications in paragraphs 15, 16 and 17 are applicable in identifying falsified medicinal products. The criteria to determine falsification will initially focus on the Customs control documentation, and any associated documentation with it, for product identity and logistical details. Associated documentation may also indicate product history. This should be followed by product labelling and packaging examination. Analytical testing should follow to determine the status of the product separate from other checks where there are continuing suspicions. These steps may be concurrent where the situation justifies it. Information provided by wholesaler or transportation agent concerned with the shipment, or even to relevant authorised manufacturers, will be necessary to assist in determining or authenticating the manufacturer's identification and the history of the product. The building of an analytical database by the Official Medicines Control Laboratories in Europe on falsified medicinal product testing would be essential in rapidly accessing possible methods and reference standards for falsified medicinal products already identified and analysed. The database should also include packaging and labelling information and representations.

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 it would not be necessary to check all these verifications?

Analytical testing may not be carried out as a first step in the enquiry as falsification may be determined by the packaging and labelling of the product. The Customs documentation relating to the product may provide the initial grounds for suspicion of falsification. Where suspicions warrant it, analytical testing should also take place to determine the finished dosage product falsification identity status separate to the labelling and packaging. This would be required where there are suspicions of one being authentic while the other falsified. Analytical testing is necessary to determine the extent of the health risk that the product poses to public health if it were to reach the market of the Union.

2. WHO PERFORMS THE VERIFICATIONS?

It is a matter for the Member State to decide on how it allocates its obligations under Article 52b. In Ireland the Memorandum of Understanding existing between the Irish Customs Administration and

the Irish Medicines Board facilitates a cooperative approach toward initial detection through to verification of the status of the medicinal product with a clear procedure for interagency cooperation. Flexibility in operation between the agencies in this activity is essential. Service Level Agreements with the Official Medicines Control Laboratory services ensures reliable analytical identification of all active ingredients that may be contained in, but not disclosed by a suspect falsified medicinal product.

Cooperation between Competent Authorities for Customs services and medicinal products regulation that facilitates appropriate control and good distribution practice inspections can ensure that falsified medicinal products can be detected in Customs control zones to prevent them entering onto the market and that the quality and traceability of medicinal products held in these areas is maintained.