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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Response European Association of Euro-Pharmaceuticals Companies (EAEPC)
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Considering that goods falling under the scope of this Delegated Act can generally be considered as "goods in transit", not intended to go into free circulation in the EEA, several scenarios are thinkable:

- *The pharmaceuticals are look alike of EU approved drugs, but do not carry the safety features needed for EU; or they have such safety features but the codes are not uploaded on any EU database, hence they fail verification; or the codes are uploaded and verification is possible by these unique identifiers*.

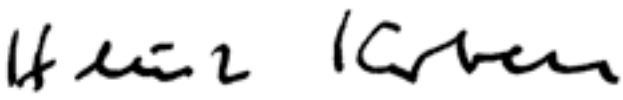
It could happen that such medicines end up inside the EEA, intentionally or not. This then constitutes a trade diversion, normally in breach of trademark law, and a falsification in the meaning of the Directive on Falsified Medicines. Ideally, when EU compatible codes are affixed, these should not be uploaded onto a repository, or if they are uploaded, they should be blocked from being verifiable.
In this context, reference is made to a diversion case from 2002, the case Glaxo Group Limited v. Dowelhurst Limited, [2003] E.W.H.C. 3060 (High Court, Ch. Div. 2003) *available at* 2003 WL 23014797; see in particular the discussion of this case in Kevin Outterson, (Associate Professor of Law, Virginia University), *Resolving dysfunctional pharmaceutical arbitrage and counterfeit drugs through the proposed Pharmaceutical R&D Treaty, November 2004.*

- *The pharmaceuticals are not registered in the EEA area, and are either brands or generics unknown in the EEA area. In these cases verification will be limited to outer packaging or analytical testing.*

In this scenario, it is critical that customs, which normally have the first contact with a consignment, are recommended to inform DRA, and that DRA can offer their medicinal expertise for any verification intended. The possible extra-territoriality of storage premises should not prevent DRA to lend their expertise; this should equally be a recommendation of the Delegated Act.

Finally the Delegated Act might recommend to Member States to establish a network of single points of contact (SPOC's) as designed by the expert working group in the Council of Europe/EDQM framework. This would make checks as proposed in points 16 and 17 more effective while respecting the usually short timelines within which competent authorities such as customs must perform these checks.

For the EAEPC,



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