SUBMISSION OF COMMENTS ON PUBLIC CONSULTATION IN PREPARATION OF A LEGAL PROPOSAL TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE

Please submit comments in editable document format (e.g. MS Word).

COMMENTS FROM German Association of Research-based Pharmaceutical Companies (VFA)
GENERAL COMMENTS
Overall VFA, the German Association of Research-Based Pharmaceutical Companies, welcomes the Commission's proposals to combat counterfeit medicines. Especially the proposed sealing of the outer packaging in combination with a track & trace system on the basis of individual serial numbering of the packages will considerably help to make the legal distribution chain safer. Yet, given the complexity of these measures, the many stakeholders which have to be involved and the considerable investments which have to be done sufficient transition time will have to be foreseen. The EU should take into account the experience in the US, where a RFID-based track & trace system should have been in place since 2007, but had to be delayed without giving a new implementation date. Therefore the sealing and the track & trace system should be introduced step by step, beginning with the medicinal products most likely to be counterfeited and with a track & trace system relying on information from the manufacturer when giving a medicine into the distribution chain and from the pharmacist when giving the medicine to the patient. Concrete implementation dates should only be set on the basis of the results of carefully designed pilot projects.

SPECIFIC COMMENTS ON TEXT

GUIDELINE SECTION TITLE		
page no. + paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
p.2, 1st bullet	The "sharp increase" of counterfeits is, most probably, not due to an increased activity of criminal organization, but due to the increased awareness of customs and a few (UK!) health authorities. Therefore, the number of seizures has increased. This should, however, not been interpreted as evidence of increased counterfeit activities.	Taking into account that the increase is, most probably, due to increased awareness and to customs activities one may assume that the real volume of the issue is, very probably, much higher. Therefore, stakeholders with customs and health authorities should be encouraged to increase their activities, in particular health authorities (outside of the UK).
p. 2, 2nd	"... trend towards counterfeiting of life-saving drugs": One may	Specify that the "trend towards counterfeiting of life-saving drugs" is

bullet	take the position that there is no such trend. From a worldwide perspective it is clear that all kinds of drugs are the subject of counterfeiting. It is only beyond question to say that the main driving factors are high value, high turnover and reduced risk of detection.	one which is linked to the internet trade where “life-saving drugs” have a particular demand.
p. 2, 3rd bullet	The perceived trend towards targeting the classical supply chain is, most probably, due to the fact that only, meanwhile, stakeholders for the “classical supply chain” really investigate the nature and volume of counterfeits. Formerly, this was based on accidental reporting, mostly.	Re-wording proposed: “The preception of counterfeits targeting the classical supply chain....”
p. 3, 2nd bullet; also 4.1.3	“Certain shortcomings in product integrity, especially when packs are opened for repackaging and changed for relabelling purposes” do facilitate the introduction of fake product.	Product integrity should be strengthened by obliging manufacturers to seal packs and traders/pharmacies to sell product only with which the manufacturer’s sealing remains intact; this combined obligation for both partners in the supply chain is crucial. Additional leaflets, labels etc., if necessary, could be taped onto the original intact box.
p.3, 3rd bullet and 4.1.4	“Difficulties in conducting targeted recalls…”	Difficulties in conducting targeted recalls and maintenance of the pedigree system could be managed by obliging traders and pharmacists to maintain and safeguard the original lot number and other identification tools (2-D-bar code etc.).
p.3, 4th bullet	“Legal uncertainty and differing practices between Member States concerning the application of pharmaceutical legislation to imports...”	.... can be solved easily by harmonising such practices. Currently, each Member State is encouraged to adopt practices on his own and each Member State court is encouraged to judge upon the legality of such practices on the merits of national views. Such flexibility per country is contradictory in this area.
p. 3 2nd last paragraph	“... unilateral action to address the problem of counterfeit medicines”	... do not understand that the phenomenon is one of a trans-border nature. Any action to solve it must be one which is made jointly by the states which share the same supply routes.
p. 4, No. 3 2nd last	“... legislative measure needs to be complemented by appropriate supervision and enforcement...”	Currently, the level of supervision and enforcement varies very much from Member State to MS. Therefore, it should be considered to adopt uniform standards of supervision and enforcement which

paragraph		are binding for MS'.
p.6, 4.1.1. 2nd paragraph	"…audits (i.e. verification of compliance with standards of an economic operator by another economic operator under the responsibility of the industry)…"	...may be reconsidered. However, it may not be very helpful to have one "grey trader" be audited by another one. Therefore, assignment of responsibility to the same type of industry should be considered on a case-by-case basis; third-party audits by accredited companies may be less questionable.
p. 8 4.1.3, 2nd bullet	"....misuse of original packs, especially when discarded after repackaging. Counterfeit products could be packaged into an outer packaging bearing safety features."	Re-use of outer packaging should be prohibited with substantial sanctions
p. 8 4.1.3, Key Ideas 2nd bullet	"….Such a requirement could be applied to certain categories of products chosen on a risk-based approach, i.e. by taking into account the public health impact of the appearance of a counterfeit product …."	Deletion of this idea is proposed. There is no evidence that fakes of some categories have less impact on patient safety than others. In contrast, each counterfeit has the same potential to harm patients, regardless of the "category" of the respective product.
p. 9 4.1.5 Key ideas	"....require the possibility to trace each pack and perform authenticity checks. This could be attained by a mass serialisation feature on the outer packaging...."	If the ban on re-boxing should not be established mass serialisation features would have to be added on the inner (= primary) packaging as well.
p. 10 4.2 last paragraph	"... it is important to stress that **the physical introduction of the medicinal product into the Community is sufficient for the rules on importation to apply**. The intention to place the product on the Community market is not required."	In this respect it is highly urgent to clarify that shipment into one of the EU Member States for transit purposed is sufficient to apply the EU laws/regulations on IP rights and counterfeiting. Thus, the basis for the ECJ case law in Class International (C-405/03, judgment of 18 October 2005) must be revised and clarified.