BPI Bundesverband der Pharmazeutischen Industrie e.V.

Comments from German Pharmaceutical Industries Association 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/ Concept paper submitted for public consultation (Sanco.ddg1.d.6 (2012)1117276)

GENERAL COMMENTS
The German Pharmaceutical Industry Association is happy to comment on the above mentioned Concept Paper. However, we find it necessary to involve all relevant authorities of the European Member States at this early stage as well.

GUIDELINE SECTION TITLE	
Line no. + paragraph no.	**Comment and Rationale**
Consultation item n°1: please comment on this above-mentioned possibility for checks and verifications (paragraphs 15, 16, 17).	The checks and verifications mentioned in paragraphs 15, 16, 17 seem to be appropriate. However, the performance of all tests in every case is not necessary. Instead, bearing in mind the statement under point 18 ("The level and range of controls and verifications should be governed by the principle of proportionality to avoid unjustified disruptions of trade flows.") the German Pharmaceutical Industry Association strongly recommends a cascade of tests in three steps – risk-based and dependent on the specific situation (see consultation item n°2). First of all, to give the authorities in charge a clear direction in which cases a falsification is likely we strongly suggest the establishment of a catalogue of criteria that lead to the performance of the above mentioned test-cascade. Those criteria to detect a falsification could be • integrity of the outer package • compliance of data in the shipping documents with those on the outer packaging (e.g. strength, batch number) • country of origin (consider to establish perspectively a catalogue of "safe countries of origin", e.g. countries without falsification incidents) • number of vendors/ brokers (increasing risk of falsification commensurate to number of brokers) Without such criteria it is likely that authorities in charge are constantly in doubt if a product is falsified and consider the whole range of checks and verifications (mentioned in paragraphs 15, 16, 17) necessary for every batch of medicinal products that enters the European Union.

SPECIFIC COMMENTS ON TEXT, page 2 of 2	
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?	If the check of the above mentioned criteria for a falsification hint to an incident, the verifications mentioned in paragraphs 15,16 and 17 should be carried out in reverse order (the above mentioned cascade). First, the shipping documents (documents concerning the distribution channels) could be requested and checked. At this stage the manufacturer of the products should be contacted. If doubts remain, subsequently information concerning the manufacturers could be requested from the importer or wholesaler of those products. Only if the first two steps justify further action, in the third grade analytical testing of the composition as well as verifications of the packaging and of the labeling might be considered. The German Pharmaceutical Industry Association would like to point out that only clear directions and procedures for the authorities in charge could help to achieve the target stated under point 18 ("The level and range of controls and verifications should be governed by the principle of proportionality to avoid unjustified disruptions of trade flows.").
Consultation item n°3: please comment on this consultation topic.	The German Pharmaceutical Industry Association fully agrees with the statements under point 20 and 21. If this cannot be achieved we expect a significant increase of cost for the pharmaceutical industry and a dramatic slowdown of speed of the distribution, in some cases with influence on shelf-life with legal and liability implications. We also ask the Commission to consider the implications of extensive testing of pharmaceutical products at the European Borders from a GSP/ GDP perspective. During the time of analytical testing the pharmaceutical products in question would have to be stored under storage conditions and in facilities that fulfil the requirements of the GSP/ GDP-Guidelines. Those facilities would have to be built and maintained by the authorities in question, a financially challenging and time-consuming procedure. Those costs and the consequences of extensive verifications at the borders of the European Union have not yet been fully calculated and have not been part of the impact assessment by the European Commission.
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.	None.