

Position Paper

Directive of the European Parliament and of the Council

amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source

2010-04-23

page 1

The Federal Association for Information Technology, Telecommunications and New Media (BITKOM) represents over 1,300 companies in Germany. Its more than 950 direct members generate a sales volume of 135 billion euros annually and employ 700,000 people. They include providers of software, IT and telecommunication services, manufacturers of hardware and consumer electronics as well as digital media enterprises. BITKOM is committed in particular to an improved regulatory framework, a modernized education system and an innovation oriented economic policy.

Preventing the entry into the legal supply chain of falsified medicinal products is one of the major challenges society and industry will have to deal with in the years to come. BITKOM therefore thanks the European Commission and European Parliament for the valuable work that has been done so far on the draft directive. Prior to the vote in committee, we would like to focus the committee members' attention on the following points:

1. **Safety features.** BITKOM is in favour of a categorisation of safety features as this is a technology-neutral approach, bringing together flexibility for pharmaceutical companies which features to use as well as to those companies and organizations offering these features (amendments 9, 80, 235, 236, 270). Moreover, both repackagers and the original manufacturer should be obliged to guarantee the same safety standards (amendment 30).
2. **Entry into force.** BITKOM is in favour of amendment 49 as an early entry into force of this legislation is expected to increase consumer safety at an earlier stage. Annual reports (as suggested in amendment 54) would be considered useful, too.
3. **Scope.** BITKOM underlines the importance to include as well OTC as prescription medicines into the scope of the directive as the authenticity of both should be guaranteed (amendments 67, 68, 69 or, as an alternative, 70). Exemptions should not be permitted (only in the case of radiopharmaceuticals), cf. amendment 74, 275.
4. **Medicinal product identification at item level** (even after repackaging) is considered to be a necessary (amendment 218), however not sufficient element to raise traceability and thus consumer safety. Item level identification should always be combined with other safety features.
5. **To secure the entire logistic chain** the system should not only include manufacturers, repackagers, and the pharmacies, but traceability of medicinal product items should also include logistics providers and wholesalers.

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