# Medicinal products for human use: prevention of the entry into the legal supply chain of falsified medicinal products

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The Commission adopted a report on the Member States transposition of Article 118a of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2011/62/EU of the European Parliament and of the Council.

As a reminder, Directive 2011/62 / EU (Falsified Medicines Directive) was adopted to address growing concerns about the presence of falsified medicines in the legal supply chain. In 2014, falsified vials of Herceptin (trastuzumab), a cancer treatment, were discovered in several EU markets. Falsification also affects medicines for sexual dysfunction and hepatitis C.

The Falsified Medicines Directive introduces mandatory safety features on prescription medicines from February 2019 (unless explicitly exempted), and establishes an EU-wide logo to allow the identification of legal online retailers of medicines (applicable from 1 July 2015).

Article 118a of Directive 2001/83/EC requires Member States to lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to the Directive and to take all necessary measures to ensure that those penalties are implemented. The penalties must be effective, proportionate and dissuasive.

This report provides an overview of the Member States transposition measures and a qualitative assessment of their effectiveness. The Commission was aided in its assessment by the TRANSPOSE study conducted by an external contractor.

Transposition of Article 118a in Member States: the main conclusion of the report is that the transposition by Member States of Article 118a is satisfactory. A total of 26 Member States have introduced changes to their legislation in relation to penalties for the falsification of medicines, active substances and excipients in order to transpose Article 118a.

All 28 Member States apply criminal penalties in the form of imprisonment for the falsification of medicines. In 21 Member States, falsification per se is penalised, without the need to prove that the product is dangerous to health. For active substances, 23 Member States apply criminal penalties. For excipients, 14 Member States apply criminal penalties.

Where criminal penalties apply for the falsification of medicines, the maximum prison sentence is at least three years in 20 Member States. All Member States apply fines for the falsification of medicines.

Effectiveness: many of the national legal experts consulted as part of the TRANSPOSE study were unable to provide estimates of the effectiveness of specific penalties in relation to falsified medicines, active substances and excipients. Experts in 10 Member States considered that all of the penalties in place (criminal, civil and administrative) had at least some effect in reducing the presence of falsified medicines in the legal supply chain. Overall, administrative sanctions were rated as effective more often.

To further reinforce measures in place and strengthen their overall effectiveness, the report concludes that certain Member States could consider introducing additional criminal penalties or administrative sanctions in relation to falsified medicines, active substances or excipients.

Member States should ensure that adequate resources and personnel are allocated to enforcing penalties in place (e.g. by training new enforcement officers). Given the difficulties in obtaining accurate estimates of the extent of falsification in the EU market, the Commission considers that increased monitoring and data collection could allow for more accurate assessment of the effectiveness of specific national provisions.

Next steps: the Commission will continue to support Member States implementation of the Falsified Medicines Directive, in particular the medicine authentication system, which becomes applicable in the Member States in February 2019.

Furthermore, the EU logo for online pharmacies should ensure that consumers do not unknowingly buy medicines from illegal suppliers and should assist Member States in their enforcement efforts.

The report stresses the importance of continued cooperation, sharing of best practices and effective monitoring of the legislation in place to discourage the falsification of medicines through suitable penalties.