COM (2008) 668 – Proposal for a Directive 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

This proposal intends to amend Directive 2001/83/EC to help prevent the entry of false drugs into the EU medical supply. False drugs are drugs that are falsified in relation to their identity, history, or source. These drugs do not meet the EU rules for medicinal products. This proposal seeks to address the insufficient provisions of Directive 2001/83/EC by: creating certain obligations for stakeholders other than wholesale distributors; making specific safety features on packaging mandatory; prohibiting the manipulation of these safety features; requiring compulsory audits of wholesale distributors; strengthening requirements for imports from third countries; and stricter rules for inspections. A public consultation was held between 11 March 2008 and 9 May 2008, but the contributions were not accessible to the research assistants. The European Parliament adopted the resolution with several amendments, including determining a concrete definition of “falsified medicinal product.” Directive 2011/62/EU came into force 21 July 2011.