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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	**Employment, Social Policy, Health and Consumer Affairs Council session on 7 December 2018** Implementation of Directive 2011/62/EU on Falsified medicinal products - *Information from the Commission*

Delegations will find in the Annex a note from the Commission services on the above-mentioned subject to be raised under "Any Other Business" at the session of the Council (EPSCO) on 7 December 2018.

IMPLEMENTATION OF THE
FALSIFIED MEDICINES DIRECTIVE 2011/62/EU

The falsification of medicines remains a serious threat to public health in the EU. There have been more than 400 incidents of falsification reported to the European Commission between 2013 and 2017. Falsified medicines can and do penetrate the legal supply chain, as exemplified by the discovery in 2014 of falsified vials of the cancer treatment Herceptin (trastuzumab) in multiple EU markets.

A key measure to address falsification in the EU and protect the legal supply chain of medicines is an end-to-end verification system introduced by the Falsified Medicines Directive[1]. The verification will take place through a medicines authentication system including mandatory safety features and a repository that stores information on each individual pack.

The new rules will become applicable on 9 February 2019. From this date, prescription medicines placed on the EU market will need to carry a unique identifier and anti-tampering device[2]. The repository system, currently being set up by stakeholders and consisting of a European hub and national databases, will need to be operational by 9 February 2019.

Marketing authorisation holders, manufacturers, wholesalers and those supplying medicines to the public (pharmacies and hospitals) will need to scan medicines at different points in the supply chain to introduce them into the repository, verify their authenticity and decommission them from the database at the time of dispense.

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1 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011on the Prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74–87).

2 In accordance with Directive 2011/62/EU and Commission Delegated Regulation (EU) 2016/161 (OJ L 32, 9.2.2016, p. 1–27).

The Commission continues to facilitate a timely and harmonised implementation of the new rules through regular contacts with national competent authorities and stakeholders, and by providing guidance upon request. In October 2018, DG SANTE, the European Medicines Agency and the Heads of Medicines Agency network published a joint letter outlining the obligations of European stakeholders under the Directive. This letter is available in all official EU languages and can be used for national outreach[3].

The Commission encourages the Member States to use these last two months before the entry into application of the safety features to renew their efforts to ensure all stakeholders are ready. It is particularly important that by 9 February 2019:

- marketing authorisation holders are able to serialise packages and are connected to the European and national databases;
- hospitals have sufficient assistance and resources to procure new scanners, IT software and staff to perform their decommissioning tasks; and
- wholesalers and persons entitled to supply medicines to the public are connected to the databases.

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3 https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/2018_letterstakeholders_safetyfeatures_en.pdf