



GLOBAL LIFE SCIENCES: EU UPDATE

Falsified Medicines Directive – Public Consultation on “Safety Features”

The EU’s Falsified Medicines Directive (Directive 2011/62/EU) forms part of the *Pharma Package*, a series of measures proposed by the European Commission in December 2008. It amends the Medicinal Products Directive (Directive 2001/83/EC on the Community Code relating to medicinal products for human use).

The Directive aims to improve drug safety by preventing falsified medicines entering the legal supply chain. The measures contained in the Directive are directed to facilitating identification of falsified medicines and improving checks and controls at the EU borders, within the EU and at all points in the supply chain.

One significant aspect of the Directive for businesses manufacturing, distributing and retailing medicinal products is the likely substantial additional cost it will impose in implementing labelling, tracking and tracing systems for their products. Others include stronger requirements for the control and inspection of EU plants manufacturing Active Pharmaceutical Ingredients (APIs), improved scrutiny of brokers and traders, sanctions against counterfeiters and obligations to report suspicions of falsified medicines.

A major aspect is a safety feature for packaging and product verification through the supply chain. The new safety feature will have to be placed on individual packs for identification, as a guarantee of authenticity, to facilitate traceability and in determining whether there has been tampering. This will also apply to repackaging where equivalent features have to be affixed.

These measures will apply to all prescription drugs unless they are specifically exempted, but not to non-prescription drugs unless they are considered to be at high risk of falsification. The Directive imposes obligations on all parties in the legal distribution chain.

The Consultation¹

The European Commission will have to decide on these safety features via the *Delegated Act* procedure. This is the new regulatory procedure for amending or supplementing non-essential parts of a legislative act, e.g. a directive, under the Lisbon Treaty.

There is currently a public consultation on supplementing the Directive that concerns the obligatory 'safety features' to allow, *inter alia*, verification of the authenticity of medicinal products ('unique identifier').

¹ On 7 December 2011, the European Commission launched a new public consultation re: the implementation of the Falsified Medicines Directive. The Commission is seeking views on how to assess the GMP regulatory framework in third countries and subsequently determine whether it is equivalent to that imposed by EU GMP rules. This topic will soon be dealt with in another Sidley Life Sciences update.

The consultation was opened by the European Commission's Directorate General for Health and Consumers (DG SANCO) on 18 November 2011. It will end on 12 April 2012. The concept paper for the consultation can be found [here](#).

The scope of the consultation is set out in the introduction of the concept paper. Notably, in relation to the Delegated Acts relating to the safety feature/identifier it specifically sets out the following:

- “The characteristics and technical specifications of the unique identifier;
- The modalities for verification of the safety features;
- The provisions on the establishment, management and accessibility of the repositories system in which information on the safety features is to be contained;
- The lists containing the medicinal products or product categories which, in the case of prescription medicines shall not bear the safety features, and in the case of non-prescription medicines shall bear the safety features;
- The procedures for the notification of medicinal products by the national competent authorities to the Commission, as regards medicinal products (not) at risk of falsification.”

Where to From Here

Member States have until 2 January 2013 to transpose the Directive into National Law. The Delegated Act setting out the safety features is scheduled for adoption in 2014, with a subsequent transitional period. The date of application of the Delegated Act is three years from the date of its publication. Accordingly, the measures are likely to be applicable from some time in 2017 onwards.

If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work.

The EU Life Sciences Practice of Sidley Austin LLP

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