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Pharmacy and the Law

Falsified medicines directive could complicate the dispensing process

Richard Hough, a practitioner in pharmacy law, looks at the implications for the dispensing process of changes in European Union requirements on traceability of medicines



There has been an alarming increase within the European Union (EU) over the past few years of medicinal products that have either been falsified or misleadingly represented in relation to their identity, history or source. These products, which pose a major threat to public health and safety, are illegal in so far as they do not comply with European Community (EC) law for medicinal products and may be referred to as "falsified medicinal products" (FMPs). They are usually unsafe, inefficient or low quality products that may contain sub-standard or falsified ingredients, no ingredients or ingredients in the wrong dosage.

Online sales from illegal, unregulated websites account for the majority of FMPs identified within the EU. However, it is not just the illegitimate supply chain that is affected by the presence of FMPs. Recently undertaken research has estimated that FMPs represent around 1 per cent of all medicinal products currently sold to the European public through the legal supply chain. Due to the increased sophistication of counterfeiters and the increased complexity of the distribution systems of medicinal products, the integrity of the legal supply chain is now under threat and this has prompted the EU's policy makers to take action.

Directive

Directive 2001/83/EC, together with the national legislation which implements the directive in each Member State, governs the regulation of medicinal products for human use within the EU. The directive's aim was to establish the functioning of the internal market for medicinal products, while ensuring a high level of public health protection. However, the directive's provisions are now regarded as being outdated and inadequate in addressing the causes of FMPs remaining undetected in the legal supply chain. In order to address these legislative deficiencies, a number of amendments to the directive have been proposed and recently accepted by the European Parliament.

The Falsified Medicines (FM) Directive,

which amends Directive 2001/83/EC, forms part of three proposals introduced in the European Commission's "Pharmaceutical Package" of measures adopted in December, 2008, and aims to protect public health by taking steps to counteract this growing problem by protecting the legal supply chain from the infiltration of FMPs. It has been described as one of the most significant European directives ever to affect community pharmacy.

“ If the proposals are fully implemented at national level there will be understandable disquiet among pharmacy contractors over cost implications and electronic infrastructure ”

The headline grabbing provisions of the FM Directive are those pertaining to the introduction of mandatory "safety features", which include authentication and traceability measures in relation to medicinal products. Other significant provisions will lead to improved regulation of internet pharmacies (in those Member States where they are permitted to operate) and more stringent sanctions against those involved in counterfeiting medicines.

Under the terms of the FM Directive, certain safety features will need to be placed on each individual pack of medicinal product so that its provenance can be determined and its authenticity and traceability guaranteed. It is envisaged, for instance, that a unique serial number will be applied to the packaging of prescription medicines, so that an electronic scan could reveal any duplication of packs

when checked against information contained in a massive centralised database. In theory, any discrepancy between the scanned serial number and the information contained in the database would alert the dispensing pharmacist that a potentially falsified medicinal product had been detected which the pharmacist could then remove from the legal supply chain. Once a medicinal product has been dispensed to a patient, the database will be required to record it as having been dispensed.

Significantly, the FM Directive allows for the safety feature requirements to be waived for generic medicines, on the basis that their low cost makes it less profitable and, therefore, less likely for criminals to falsify them. The safety feature requirements will also not apply to non-prescription medicinal products, though they may be applied in future once the effect of those for prescription medicines have been assessed.

The safety feature requirements also include a prohibition in principle of manipulating (ie, removing, tampering with or over-labelling) safety features on packaging by those parties situated in between the original manufacturer and the last party in the distribution chain, typically the pharmacist. Parties such as parallel importers who are involved in the repackaging of medicines will be required to replace the original safety features of a product with equivalent ones. This prohibition of package manipulation should also allow pharmacists to ascertain if the outer packaging has been tampered with prior to dispensing.

As a separate but related point, Member States will also be required to ensure that no collection or commercial processing of data generated by the use of the safety features takes place that would enable a link to be made between a medicinal product and the patient to whom it is provided.

Internet pharmacies

All internet pharmacies operating within the EU will need to be specially authorised by a competent authority before medicinal products can be supplied to the public. They will also be required to adhere to professional standards and to display a logo, which will be recognisable throughout the EU, on the front page of their websites so that the public can be assured that they are linked to an authorised internet pharmacy. The logo will be linked to a centralised website at Member State level, which will allow the website visitor to check the authenticity of the logo and receive reassurance that the website they are visiting is a regulated one. The centralised website will

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also provide information pertaining to the risks of buying medicinal products through the internet.

The FM Directive also states that effective sanctions should be imposed for acts involving FMPs which should be at least equivalent to those which would be typically applied for illegal acts involving narcotics.

Other provisions of the FM Directive include:

- Certain obligations (eg, compulsory licensing) being placed on parties other than wholesale distributors, who act in the distribution chain of medicinal products (eg, traders or brokers) who may be involved in transactions without actually handling the products

- Obligatory audits of wholesale distributors of medicinal products

- The strengthening of requirements for imports of active pharmaceutical ingredients from non-EU countries, if it can not be established that the regulatory framework in the non-EU country ensures a sufficient level of protection of human health

- Audits of manufacturers of active pharmaceutical ingredients

All Member States will be required to implement a system to prevent fake or poor quality medicines from reaching patients, including a system that can issue recalls — if an FMP reaches patients an alert must be issued within 24 hours.

Impact on pharmacy

The directive's aims are laudable and its impact will certainly be felt by community pharmacists, not least as the way is now paved for electronic verification of medicinal products at the point of dispensing, although it must be stressed that the system of verification is yet to be decided upon and it will be left to the European Commission to ensure that any pan-European traceability system, which should be adopted by no later than February, 2014, is comprehensive, harmonised, efficient and effective. If the proposed measures are fully implemented at national level there will be understandable disquiet among pharmacy contractors over the cost implications of implementing the proposals, the reliability of the electronic infrastructure which will need to be introduced to run the traceability system and the operational difficulties of being required to verify branded prescription medicines but not having to do so for generics.

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