BMA

England

Focus on the Falsified Medicines Directive

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Background

Following adoption by the Council and the European Parliament, the Falsified Medicines Directive (Directive 2011/62 /EU) was published on 1 July 2011 in the Official Journal of the European Union. The Falsified Medicines Directive applies since 2 January 2013.

The Directive introduces tougher rules to ensure medicines are safe and that the trade in medicines is rigorously controlled. This is a reaction to a reported significant increase of false medicinal products detected within the legal supply chain of the Member States. Counterfeiting high-price medicines is perceived as a growing illegal business and a threat to public health worldwide.

In order to tackle the problem a number of measures are proposed:

- The introduction of safety features to ensure full traceability of each individual package of high-risk products so identifying more easily false representations of medicinal products;
- Improving the control at the EU external borders through which false medicinal products could enter; and
- Ensuring the active pharmaceutical ingredients are of high quality standard and not falsified.

This is a significant change that will affect all those in the pharmaceutical supply chain. It should also be noted that it is unlikely to be affected by the recent decision to leave the European Union; the Directive is already incorporated into UK legislation and is almost certain to be implemented.

What will happen next?

The legislation will become effective on 9th February 2019. This may seem like a long way off, but these are significant changes and practices need to be ready and to develop, test and input new systems and working practices, all of which will take time.

What is proposed?

The Directive will impact on all stakeholders and will need to be considered by manufacturers, wholesalers and dispensers with an aligned approach.

More specifically, the legislation will require all prescription medicines for sale to carry a unique and randomised serial number encoded in a 2D-barcode and a visible anti-tampering device.

It will be the responsibility of manufacturers to upload the serial numbers to a system of national databases linked by a European hub, while country-based national data repositories will allow verification at different times and final decommissioning when each pack is dispensed to a patient.

At each stage of the supply chain, the product will be inspected to ensure it hasn't been tampered with, has not previously been dispensed and that the packaging remains intact. Additionally, goods distribution practice guidelines will require the individual product to be scanned to record the batch number and expiry date. This check will indicate whether the product is authentic and bring up information such as whether the product has been subject to a recall.

Implications for practices

As noted above, plans to implement the European Falsified Medicines Directive are expected to continue, despite the UK's recent decision to leave the European Union. A key issue is therefore who will fund the new dispensary and wholesaler equipment.

It is anticipated that under the Directive, wholesalers and practices will each verify most prescription medicines: wholesalers at the point of receipt (and when returned) and dispensaries at the point of dispensing.

The Directive stipulates that the cost of the creating and maintaining the data repository will be paid for by manufacturers. However, they will not be obliged to bear the cost of providing connectivity to the database or for the IT hardware and software that will be required in every pharmacy.

The General Practitioners Committee of the BMA has concerns the authentication system will result in burdensome bureaucracy for pharmacists and that it will not fit in with pharmacy IT systems, creating a significant financial impact in implementing the system (e.g. software, hardware and training).

This comes at a time when practices are already facing the challenge of putting into effect the Electronic Prescription Service; an NHS Service that will enable GP surgeries in England to send prescriptions electronically for dispensing by an EPS compliant dispensary. The benefits of both will only be fully realised if NHS England finds the resources to fund practice IT and internet connections that can cope with both.