BMA

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 had to be transposed by member states by 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 any prescription item, 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 a high quality standard and not falsified.

This is a significant change that will affect all those in the pharmaceutical supply chain.

What will happen next?

The legislation will become effective on 9th February 2019. The Government has agreed to adopt the Directive, which means practices should be preparing for implementation and be able to demonstrate compliance with the Directive.

What is proposed?

The Directive will impact on all healthcare bodies in the supply chain including dispensing and non-dispensing GPs, 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.

The unique identifier comprises:

- a product code, which allows the identification of at least the name of the medicine, the common name, the pharmaceutical form, the strength, the pack size and the pack type
- a serial number which is a numeric or alphanumeric sequence of a maximum of 20 characters randomly generated
- a batch number
- an expiry date

It will be the responsibility of manufacturers to upload the serial numbers to a system of national databases linked by a European hub (although only 15% of products are expected to be compliant from February), 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 has not 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.

On supply to the patient, the unique identifier must be 'decommissioned' via a scan from the FMD system, to prevent any duplication of a legitimate identifier for use on a falsified medicine. This will be checked against data in the national repository.

All practices will need to have the infrastructure and processes in place to decommission medicines, even non-dispensing practices that prescribe and administer vaccines. They will also need to decide whether they decommission medicines at the point of dispensing or in advance, although practices should take into consideration the proposed 10-day window in which they will be able to recommission the medication into the system.

Implications for practices

As noted above, plans to implement the European Falsified Medicines Directive are expected to continue, despite the UK's decision to leave the European Union. SecurMed UK is the not-for-profit company set up to establish the UK Medicines Verification System as required under the Directive. They are working with all stakeholders across the medicines supply chain and are overseen by the Department of Health and Social Care, to implement FMD in the UK.

Under the Directive, wholesalers and practices will each verify most prescription medicines: wholesalers at the point of receipt (and when returned), dispensaries, pharmacies and healthcare institutions at the point of dispensing.

The Directive stipulates that the cost of 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. Therefore, we expect this to be provided by the NHS.

The General Practitioners Committee of the BMA has concerns the authentication system will result in burdensome bureaucracy for pharmacists, practices and dispensing doctors and that it will not fit in with current pharmacy/dispensary IT systems. This is likely to result in an increase in the time taken to dispense, thereby representing an increase in workload.

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 the NHS finds the resources to fund practice IT and internet connections that can cope with both.

Recent developments

As part of the government's preparations to leave the EU, all eventualities are being considered including leaving without an agreement. In a 'no-deal' scenario, we expect the UK would not have access to the EU central data hub, and therefore stakeholders would be unable to upload, verify and decommission the unique identifier on packs of medicines in the UK. In that case, it is unlikely that the Directive would come into effect in its current form.

Therefore, the legal obligation related to this would be removed for practices in the UK supply chain. Packs containing the FMD safety features would still be accepted in the UK, provided that they are in line with other UK packaging requirements.

Nevertheless, the government has been clear that it wants to retain a close working partnership with the EU to ensure patients have access to a safe medicine supply. This means that the MHRA regulations will need to be modified to achieve this.

What the BMA is doing

The Directive was adopted in June 2011 and was transposed into UK law in January 2013 with the exception of the rules in relation to the safety features set out above. Notwithstanding the possibility of a 'no deal' scenario, members should assume the Directive will be implemented fully in February 2019 and prepare accordingly.

However, the BMA has met regularly with the Department of Health and Social Care and others involved in the implementation of the Directive to ensure that the interests of GPs are represented and any adverse implications of its introduction on practices are mitigated.

The BMA has argued strongly that the NHS must fund the equipment required and make the necessary IT equipment available to facilitate the Directive so that the impact on the workload of GPs and their employees is kept to a minimum.

Further information

For further information, please email info.gpc@bma.org.uk.