Falsified Medicines Directive
January 2019 update for members

Background

The EU Falsified Medicines Directive (2011/62/EU) (FMD) was adopted in 2011 and introduced new harmonised measures to ensure that medicines in the European Union (EU) are safe and that trade in medicines is properly controlled.

Member States have until 9 February 2019 to implement the final part of the Directive, the 'safety features' (Delegated Regulation (EU) 2016/161). Under Article 23 all GP practices and dispensing doctors are identified as healthcare institutions and will have to comply with the Directive. It is for the member state to implement and enforce the Directive. GPC has produced a 'Focus on' document to assist GP practices.

Key messaging

Although the go live date is imminent, the key message is there is no need to panic. The UK will still be a member of the EU on 9 February. Therefore, the Directive will be implemented regardless. If no deal is secured, then the UK will leave the EU on 29 March and the Directive will not constrain us. Plans are being laid before Parliament related to a no deal scenario, but obviously some uncertainty remains, particularly as there are some statutory instruments which need to be laid.

EU readiness

GPs may be concerned that the UK is behind the curve. In fact we are relatively well-placed. Italy has a dispensation to implement at a slower pace (because they have a similar system in operation already). Spain is showing red on the dashboard for implementation; however, they plan to upload all their pharmacies in the next two weeks. They could run into problems if they have IT glitches. In France, there is a dispute between the government and pharmacies, so nobody is currently registered. Norway is 95% there. The UK has a plan for moving towards full implantation. Pilot sites using the EU repository had some issues with a slow system, but that has been resolved.

UK readiness

Implementation is the responsibility of the Department of Health and Social Care and the Medicines and Healthcare products Regulatory Authority. They are taking a pragmatic view. Manufacturers are producing the tamperproof and bar-coded products. There are regular meetings with the NHS supply chain, and there remains the dual challenge of making sure that the supply chain is operational following our exit from the EU as well as the introduction of FMD. On 9 February products coming from manufacturers should be FMD compliant. There will still be old stock available, so it will take some time before the new packaging percolates through the supply chain. So going forward from February/March we will have products produced before 9 February that will not be able to be decommissioned, even if practices have the equipment and then there will be products that have the unique identifiers which can be decommissioned if practices have the appropriate scanning equipment. Medication will still be able to be issued, but it won't be decommissioned on the EU system.

Legislation

All statutory instruments are at risk because parliamentary time is being used to try and secure a deal for our exit from the EU. NHS England has stated that system suppliers will be ready shortly, but there will be a slower implementation phase. We are expecting, and are pushing, for a full statement from NHS England.

Secure Med UK

Secure Med is the UK medicines verification organisation. End users will have to register. GP practices are not required to pay any licence fees. GPs could register now, but will need to identify their software supplier, and for that to be possible, system suppliers and NHS Digital will have to act. Practices are not being encouraged to purchase their systems, although there are some on the market. Some dispensing practices and GP practices have registered so far, but the majority will wait until they know what the offering is from NHS digital and their software suppliers. The BMA position has been that the equipment and costs must be provided. We are expecting a statement from NHS England shortly. GP system suppliers will be introducing functionality, but there will be a long lead-in time. There are likely to be early adopters who will test the system in March 2019. End users can register via the Secure Med website. The early adopters will test the real life experience of the workload, workflow and technical difficulties utilising the system.

Communication

There are regular newsletters, and full details can be available on the Gov.UK website. www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features

Enforcement

GPC expects regulators to take a pragmatic approach and a gradual introduction, however it appears that almost everyone in Europe will not be compliant on day one. UK regulators are responsible for taking any action. No legal action could be taken without enforcement notices being applied, and at present it appears unlikely that anybody will be served such a notice, however this may change.