surrey and sussex lmcs

To: All practices in SSLMCs Confederation

19th October 2018

Dear Colleagues

Falsified Medicines Directive (FMD)

The EU Falsified Medicines Directive (FMD) has been introduced across the European Union to address the increasingly common issue of falsified medicines entering the legitimate medicines supply chain. Falsified medicines include those with little or no active ingredients, the wrong active ingredient, fake or tampered packaging, or stolen products. Their existence poses a safety risk to patients and undermines confidence in genuine products.

The Directive comes into force on 9th February 2019, although implementation will be phased. New medicines marketed in Europe will have two safety features:

- a unique identifier (UI) in the form of a 2D data matrix (barcode): if space permits, this will also be in human readable form
- an anti-tampering device.

Each participating county will have a National Medicines Verification System (NMVS) via which manufacturers will be able to upload valid UIs; these will then be active. Manufacturers will then be able to withdraw UIs if these are known to have been tampered with, stolen, or withdrawn.

The next step will be for pharmaceutical wholesalers, community and hospital pharmacies, dispensing GP practices, and others 'authorized to supply medicines to the public' to scan the UI and send details to the NMVS which will compare this information with that provided by the manufacturer. If the two are confirmed, the dispenser can then send another message to the NMVS converting the medicines status to 'inactive', thus preventing duplication. As part of this process the anti-tampering device will also be checked.

Almost all prescription products with a Marketing Authorisation will be within the scope of the FMD; unlicensed products (with a few possible exceptions) and medical devices will not be covered.

The substantive implications of the FMD will be within Community (and Hospital) Pharmacy, but dispensing GP practices are also likely to have to operate parallel systems: dispensing practices can obtain additional information via the Dispensing Doctors Association. There are likely to be cost implications, since at present dispensing bodies themselves will have to pay for the scanning equipment, to identify UIs, and IT software programmes, to comment and communicate with NMVS. There will also be implications for returning stock.

Local Medical Committees for
Croydon, Kingston & Richmond, Surrey,
East Sussex and West Sussex

The White House
18 Church Road
Leatherhead
Surrey KT22 8BB

T: 01372 389270
F: 01372 389271

www.sslmcs.co.uk

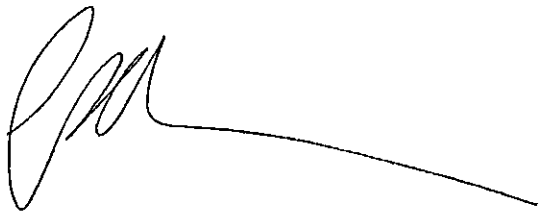
In terms of Brexit, the EU Directive will come into force prior to the UK's currently scheduled exit from the EU, and the EU Withdrawal Act converts existing EU law into UK law, and so the Directive will still apply unless revoked. The Government also intends to maintain a "high regulatory alignment" with the EU and given the UK's global pharmaceutical sector, it is highly likely the UK will continue to comply with the FMD.

The GPC have advised roll-out after February 2019 is likely to be incremental, and indeed at that point probably less than 20% of medicines on the market with have UIs and anti-tamper devices, and the bar-code readers will not be widely available.

If at this point, colleagues wish to know more, the DDA website is available to members: there is also a comprehensive description of the background and current status at https://fmdsource.co.uk although this is written with Community Pharmacy colleagues in mind. It is unlikely non-dispensing practices will be affected in the short term, and for them, but not dispensing practices, the impact of FMD is likely to be small.

With best wishes

Yours sincerely



Dr Julius Parker
Chief Executive