Dear IDF Members,

I am writing to you regarding the introduction of the Falsified Medicine Directive. With the deadline for implementation fast approaching, the GP Committee felt it important to update IDF GPs. Hopefully NHS England are releasing guidance for GPs imminently.

The Falsified Medicines Directive is an EU initiative. This legislation comes into force on 9.2.19. It is being introduced to improve the safety of medicines and address concerns about counterfeit drugs being circulated in the European market.

Who does it affect?

The Directive will impact on all healthcare bodies in the supply chain. Under Article 23, GP practices and dispensing doctors are identified as healthcare institutions and will have to comply with the Directive. This includes both dispensing and non-dispensing GPs as it is likely to affect vaccines and personally administered items. It will also need to be considered by manufacturers, wholesalers and dispensers with an aligned approach. The scope of FMD covers all prescription only medicines (POMs) as set out in regulation 2016/161/EU. There are some exceptions to the regulations for some medicines listed in Annex I and Annex II Delegated Regulation.
The Process
Under the directive, all new packs of prescription medicines placed on the market in Europe from 9.2.2019 onwards will have to bear two safety features: a unique identifier (UI) in the form of a 2D data matrix (barcode) and an anti-tempering device (ATD).

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

Manufacturers will upload valid UI codes to a European Hub, which will then pass data to the relevant National Medicines Verification System (NMVS) and so it will be able to check the status of each pack during the dispensing process. The system will be notified of products known to have been recalled, withdrawn, stolen or tampered with. The European Medicines Verification System (EMVS) will act as the European hub, linking the national systems together and allowing parallel trading of medicines to continue.

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.

Secure Med UK is the UK medicines verification organisation. End users will need to register. GPs could register now, but will need to identify their software supplier.
Where GPs can get further advice

There is plenty of advice online. There are regular newsletters, and full details can be available on the Gov.UK website. There seems to be conflicting advice regarding the Brexit situation.

The IDF cannot give individual advice but I would advise you look at the websites below and also ask advice from your wholesaler, pharmacist or hospital.

https://www.securmed.org.uk/what-is-fmd/
https://www.securmed.org.uk/faq-dev/
https://fmdsource.co.uk/introduction-to-fmd/
https://www.bma.org.uk/advice/employment/gp-practices/service-provision/falsified-medicines-directive

What to do now

Although the go live date is imminent, the key message from the BMA is there is no need to panic. I would encourage you to read the link below regarding the BMA and DDA advice released on 24.1.2019. A detailed statement from NHS England is expected this week.


Best wishes,
Dr Di Loudon,
IDF GP Committee Chairman