

Falsified Medicines Directive

Dear DDA member

I am writing to you regarding the implementation of the EU Falsified Medicines Directive (FMD) on Saturday 9 February. You can find the details about the directive itself on our [website](#).

Please remember that the FMD applies to all GP practices, not just dispensing.

Many of you have contacted us, and posted messages on our [Facebook group](#), requesting further information and asking what the DDA is doing. So far, all we have been able to say is that we are awaiting a detailed statement from NHS England, which owns and pays for your practice IT and secure internet connection. Many of you are very concerned that you will be found in breach of the FMD following the implementation.

The DDA deeply regrets the lack of information available and shares your frustration at the lack of progress. I have been expressing concerns about this matter to those in authority for well over two years. With the GPC/BMA we have been demanding that NHS England, and the health departments in the devolved nations, provide the necessary funding for practices to become compliant with the FMD.

Yesterday, I attended a meeting of the Implementation Advisory Group (IAG) for the FMD, which is hosted by the Department of Health & Social Care (DHSC) and the Medicines Healthcare Regulatory Agency (MHRA). The MHRA has responsibility for the legal enforcement of the FMD.

At the meeting, I expressed deep concern that NHS England has still not informed practices of its intentions. I was told that a statement is expected "this week". This is the same response that I received at a meeting last week, which demonstrates the difficulties the DDA is experiencing.

In England, your practice IT systems are provided and paid for by the NHS and there are strict rules regarding the connection of new hard/software to those systems, in addition to the secure internet connection. It is for this reason that our advice remains for you not to invest in new kit, which may not be clinically integrated, may even be defunct within months, and not refunded by the NHS. When an announcement is made by NHS England, it is likely that the implementation will take some months.

There are some developments to be aware of, however:

England: NHS Digital will shortly be requesting some English practices to volunteer to pilot the FMD IT. DDA members are urged to volunteer. More details to follow.

Scotland: The Scottish government has recently announced a one-off payment of £2,000 for dispensing practices to purchase and install kit to comply with the FMD. Our understanding is that the health department does not intend to be prescriptive about the systems, or the process, for installation of the equipment. The DDA is liaising with the Scottish GPC/BMA about this and will offer specific guidance as soon as possible.

Wales/Northern Ireland: At present, the intention of the administrations in Wales and Northern Ireland is unclear and we are working with the GPC/BMA to establish the position.

Nonetheless, we would now advise all practices to register as a 'requestor' with SecurMed UK which is the national repository for the FMD. Registration is free and [online](#).

Even if you are unable to complete your registration, for example, because you will currently lack details of the approved GP IT supplier/s, registering as a requestor demonstrates that you are complying with the FMD. Full registration can take place once there is clarification on the funding issue by NHS England. There is more information on managing incomplete registrations and choosing an FMD supplier on the SecurMed UK [registration portal](#).

Finally, many of you have expressed concern about the consequences of not being fully compliant with the FMD by Saturday 9 February. The MHRA has the responsibility for taking the decision whether to take action against a contractor for non-compliance. The MHRA has made it clear to the DDA that it will take a pragmatic approach, given that it is now impossible that all GPs (and many other contractors in the NHS) will be compliant by 9 February. This is also the case in many other EU countries.

Registration as a requestor with SecurMed UK, your response to the announcement by NHS England (when it appears) and, for Scottish practices, action following receipt of the FMD payment, all demonstrate that action is being taken to comply with the FMD. The DDA is currently speaking to BMA Scotland and will be issuing advice to Scottish members as soon as a joint approach to implementation in Scotland has been agreed.

In the meantime, please do not worry about the deadline. Should you be told anything to the contrary by NHS managers or anybody else in authority, please inform the DDA immediately and we will raise this with the MHRA.

The DDA will keep you informed of all developments via our website, our email alerts and Facebook group. If you are not a member, please request access now.

Thank you for your continued support.

Matthew Isom
Chief Executive
Dispensing Doctors' Association Limited