UK FMD working group response to

MHRA

Consultation

On

Implementing 'safety features' under the Falsified Medicines Directive

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The UK FMD Working Group for Community Pharmacy

The UK FMD Working Group for Community Pharmacy brings together all the main pharmacy bodies representing community pharmacy to influence and inform implementation of FMD in the UK. The group comprises expert representatives from AIM, CCA, CPNI, CPS, CPW, NPA and PSNC. It meets regularly with DHSC, MHRA, GPhC and NHS Digital to discuss how FMD will operate in UK pharmacies and to seek practical and pragmatic solutions for its implementation.

General remarks

The UK FMD working group welcomes the opportunity to respond to the MHRA consultation on implementing 'safety features' under the Falsified Medicines Directive, and asks for further clarification on a number of points.

In paragraph 1.3, the consultation suggests, *"medicines will be able to be authenticated on a risk-based approach through the supply chain with verification and decommissioning (changing the active status of the product in the national and European repositories to prevent any further verification) taking place before the product is supplied to the patient*". The FMD working groups asks whether the phrase "further verification" should say "further deactivation" instead.

In Paragraph 1.10, the consultation refers to *"Community pharmacy guidance (CPA)"*. The UK FMD group asks if this is a reference to the group's publication *"The Way Forward for FMD in Community Pharmacy"*. The group is happy for its website (www.fmdsource.co.uk) and content to be promoted.

In Paragraph 1.14 the consultation suggests that GPs and dispensing doctors be classed as health centres and therefore healthcare institutions. It concludes saying "we would expect Dispensing Doctors to decommission as pharmacies". The UK FMD working group believes that it is important that the same authentication requirements apply across primary care. We therefore suggest that dispensing doctors 'must' face the same requirements as community pharmacies. We ask whether the requirements will also apply in instances of direct supply from the manufacturer to GP surgeries, including flu vaccinations and any other medical supplies.

We suggest that consultation proposals lead to an inequity between hospital outpatient pharmacies, with some being required to authenticate at the time of supply to patients and others being able to undertake this process at an earlier point. This anomaly should be addressed.

Brexit

Brexit is a source of uncertainty for the longevity of FMD in the UK. Continued access to the EU FMD hub will depend on the future relationship between the UK and the EU. We note that the UK government is negotiating a transition agreement with the EU and is seeking close alignment on medicine policy. We call on the government to ensure continued access to the EU hub during the transition period, and beyond.

However, if there is no transition agreement, access to the EU hub will cease just seven weeks after FMD scanning commences. Even if there is a transition agreement, access to the EU hub may end after the two-year transition period. As a result, community pharmacy are left not knowing how long the FMD system will be needed for. It might be needed for 7 weeks, or 2 years, or far longer. Community pharmacies will therefore need to consider carefully the contract they sign with FMD system suppliers, especially where it relates to contract length and early exit clauses.

We believe that Government must be candid with the sector to ensure that already hard-pressed community pharmacies are not required to invest in FMD systems if the need to decommission is not going to endure. If community pharmacies must comply, and based on current government statements it appears they must, then the government must fully compensate community pharmacy for the additional burden of the FMD regulations in the next funding round. We further ask that in the event of the UK medicines verification system being disconnected from the European hub, that the government cover all costs associated with transforming the UK FMD system into an independent UK FMD system.

Overall, the working group believes there should be a proportionate and risk-based approach to the implementation of the safety features part of the Directive that allows patient safety and integrity of the supply-chain to be assured while not undermining the efficiency and cost-effectiveness of dispensing in community pharmacy.

Questions:

Question 1: What form of sanctions regime do you think would be the most effective to enforce the regulations across the UK medicines supply chain?

We agree with the proposal that, other than in exceptional circumstances, such as intentional fraud, civil rather than criminal sanctions are used to deal with non-compliance. We believe that any sanctions must be fair and proportionate. Isolated non-compliance, such as failures to scan products, do not undermine the integrity of the system, which has been designed to remove the economic incentive to insert falsified medicines into the supply chain. It would therefore be inappropriate to apply any sanctions for isolated failures to comply.

Currently, community pharmacy contractors face a great deal of uncertainty in regard to the financial, operational and patient safety impact of FMD and the exit of the UK from the EU amplifies the uncertainty and potential risk. Overall, the working group believes there should be a proportionate and risk-based approach to the implementation of the safety features part of the Directive that allows patient safety and integrity of the supply-chain to be assured while not undermining the efficiency and cost-effectiveness of dispensing in community pharmacy.

Question 2: Can you provide any additional evidence or comment on the existing impact analysis to develop the cost benefit analysis in the impact assessment?

No.

Question 3: Do you agree with the Government's proposed approach not to extend the requirements for the unique identifier or anti-tampering device to any additional products at this time?

Yes

Question 4: Do you agree with the Government's proposed approach not to require a reimbursement number, or other national number identifying the medicinal product, to be placed on products bearing the safety features?

Yes

Question 5: Do you agree that manufacturers should be allowed to include information other than the unique identifier in the 2D data matrix code?

We could only support this if the following concerns are taken into account. Other MHRA-authorised information should be allowed within the 2D Data Matrix, if it does not slow the system down significantly; and there must be no expectation that the pharmacist will utilise any such data or pass it to the patient or their representative. Clarity on this is needed to ensure responsibility and liability are properly defined. Pharmacists and other pharmacy staff must not be distracted from the dispensing process.

Question 6: Do you agree with the Government's proposal to put in place provisions requiring wholesalers to verify and decommission medicinal products bearing the safety features before supplying them to any Article 23 provider authorised to supply medicines to the public?

No response.

Question 7: Do you agree that there is no practical benefit to exempting persons operating within a healthcare institution in the UK from the obligations of verification and decommissioning under the conditions set out in chapter 5?

No response.