MHRA Consultation: Implementing ‘safety features’ under the Falsified Medicines Directive

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About the Company Chemists' Association (CCA)

Established in 1898, the CCA is the trade association for large pharmacy operators in England, Scotland and Wales. Our membership includes ASDA, Boots, LloydsPharmacy, Morrisons, Rowlands Pharmacy, Superdrug, Tesco, and Well, who between them own and operate over 6,000 pharmacies, which represents nearly half the market. Our members deliver a broad range of healthcare and wellbeing services, from a variety of locations and settings, as well as dispensing almost 500 million NHS prescription items every year.

The CCA represents the interests of its members and brings together their unique skills, knowledge and scale for the benefit of community pharmacy, the NHS, patients and the public. Our vision is that everyone, everywhere, can benefit from world class healthcare and wellbeing services provided by their community pharmacy.

Our response

We welcome the opportunity to respond to this consultation and, as a member of the UK FMD Working Group for Community Pharmacy, the CCA has also contributed to that collective response which we fully endorse. In addition to the consultation questions we address directly, we also set out a number of overarching key points immediately below.

Similar to the FMD Working Group, we believe there should be a proportionate and risk-based approach to the implementation of the 'safety features' aspect of the Falsified Medicines Directive (FMD). This is in order that patient safety and integrity of the supply-chain can be assured, while not undermining the efficiency and cost-effectiveness of dispensing in community pharmacy.

It is inevitably difficult to respond to this consultation without considering the impact that the UK exiting the European Union will have upon implementation. Community pharmacy businesses, and wider pharmacy, simply do not know how long the FMD system will be in place, because we do not know what agreement the UK Government and European Union will come to in this area. In this situation of uncertainty, pharmacy businesses are nevertheless having to enter into legal agreements and make financial investments in IT, staff training and other operationalisation platforms with FMD system suppliers despite, not knowing if they will be required on an ongoing basis.

We agree with the FMD Working Group that the Government must be open and transparent with the pharmacy sector. This is to ensure that community pharmacy – which is already financially challenged, is not required to invest in FMD systems if they will not be needed into the future. If community pharmacies remain required to comply with these new aspects of the Directive, we believe the additional cost burden should be taken into account within any new NHS funding settlement. In the event of the UK medicines verification system being disconnected from the European hub, we similarly agree with the FMD Working Group that the Government should fully compensate the sector financially, where all or part of the system which has been invested in becomes redundant.

We also agree with the UK FMD Working Group that believes it is important that the same authentication requirements apply across primary care and that dispensing doctors fulfil the same requirements as community pharmacies. Furthermore, we would like to know if these requirements also apply in instances of direct supply from the manufacturer to GP surgeries, including flu vaccinations and any other medical supplies. We would not agree with any unnecessary inconsistency between community pharmacy and hospital outpatient pharmacies, where some are

required to authenticate at the time of supply to patients and others are able to undertake this process at an earlier point.

Below is our response to the consultation questions.

Consultation 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?

Civil sanctions
We agree with the proposal that, other than in the most serious cases - such as wilful non-compliance or fraud that breaches the integrity of the system, a civil - rather than criminal - sanctions regime should apply. We believe that any instances of law enforcement to address non-compliance with the Directive, and application of sanctions, must be fair and proportionate.

Risk of accidental non-compliance
We are conscious that implementation of FMD safety features in the UK is being rolled out system-wide at pace. This requires all parts of the process - from manufacturing to dispensing, to invest in new IT and scanning systems and modify their standard operating procedures and workflows, based on a new national IT platform that is interoperable with the European hub. This is all in the context of significant uncertainty arising from the UK exiting from the European Union.

Managing change effectively
All elements of this change-process introduce new and additional financial, operational and reputational risk for community pharmacy businesses. We would not expect a punitive legal approach to any instances of unintended non-compliance in the early stages of implementation, but rather we call for an opportunity for local, company-level and system-wide learning and development -with a reasonable period of post-implementation evaluation. We are mindful that the supply-chain into community pharmacy must not be undermined at any stage because it could cause inefficiency, introduce unnecessary costs and jeopardise access to dispensed medicines by patients.

Future uncertainty
It is inevitable that exiting the European Union creates significant uncertainty for the ongoing feasibility and longevity of the FMD's applicability in the UK, and the ability of community pharmacy to undertake informed planning and investment. The consequence is that community pharmacy businesses are now having to invest in new equipment, modification of standard operating procedures and staff training for systems that may last years, or alternatively only weeks or months. To provide some assurance this will not be wasteful, we call on the Government to ensure continued access to the EU hub during the transition period, and beyond. We are also concerned that if there is no transition agreement between the UK and EU, access to the EU hub would end shortly after FMD scanning commences.

We believe there must be more clarity and certainty on this as soon as possible, not least to ensure that no community pharmacy business is found to be unintentionally non-compliant with a prevailing law due to whole or partial system failure or uncertainty.

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?

Yes. Additional MHRA-authorised information should be allowed within the 2D Data Matrix, where that does not affect the system operation adversely. However, intellectual property ownership, data protection and data-usage must be clearly defined, and the system must not be over-burdened in a way that compromises the system operationally or introduces administrative burdens on community pharmacy businesses.

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.

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