



Community  
Pharmacy  
Scotland

## **FMD Safety Features Consultation**

**Prepared by:**

Amanda Rae  
Head of Policy & Development  
[amanda.rae@cps.scot](mailto:amanda.rae@cps.scot)

# Who are Community Pharmacy Scotland (CPS) & what do they do?

## Who we are

We are the organisation which represents community pharmacy contractor owners in almost every aspect of their working lives, and are the voice of these vital healthcare professionals as they deliver pharmaceutical care to the people of Scotland.

We are empowered to represent the owners of Scotland's 1256 community pharmacies and negotiate on their behalf with the Scottish Government. This covers all matters of terms of service and contractors' NHS service activity including remuneration and reimbursement for the provision of NHS pharmaceutical services.

## What we do

We work with the Scottish Government on the development of new pharmaceutical care services and ensure that the framework exists to allow the owners of Scotland's community pharmacies to deliver these services.

The Scottish community pharmacy contract puts the care of the individual right at its centre and with its focus on pharmaceutical care and improving clinical outcomes, community pharmacy contractors and their employee pharmacists are playing an increasingly important role in maximising therapeutic outcomes and improving medicine safety. Community pharmacy is at the heart of every community and plays an important part in the drive to ensure that the health professions provide the services and care the people of Scotland require and deserve.



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## **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?**

Community Pharmacy Scotland (CPS) would like to see a similar approach to that of the General Data Protection Regulation (GDPR)

Suggested text “If community pharmacists can demonstrate they have the appropriate systems and thinking in place for FMD, then the regulator should be proactive and pragmatic, aware of business needs and the real world. “

The option to use a mixture of civil and criminal sanctions is preferred. Civil sanctions, including written warnings and stop notices should be the first formal sanction, implemented after informal intervention, followed by civil fines if required.

Criminal sanctions should only be used for the most serious, intentionally fraudulent breaches.

## **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?**

Article 23 is not applicable to Community Pharmacy and therefore not relevant for significant comment from CPS.

Option One: require wholesalers to decommission on behalf of Article 23 providers

is, in our opinion the preferred option. It represents the best value for money of the UK options available.

**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.

There is no evidence to support the need for this extension, and it would create an additional burden on other areas of the business, in excess of any benefits created.

The UK allows manufacturers to add anti-tampering devices where they feel it is appropriate and this will remain an option.

**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.

This would add extra constraint to the packaging requirements and complicate the supply of multi-national packs. Products will be mapped to UK NHS identifiers through information already required by authorisation holders which will provide all that is required.

**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, provided this does not slow the function of the community pharmacy system.

**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?**

Article 23 is not applicable to Community Pharmacy and therefore we have no comment to add.

**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**

This is not applicable to community pharmacy and therefore CPS has no comment to add.