



Community
Pharmacy
Scotland

**Informal Consultation on Urgent Changes to the Human
Medicines Regulation 2012 to ensure the Continuity of
Supply of Medicines
(Including In A 'No Deal' Brexit)**

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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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1. Do you agree with the introduction of the provision for a 'serious shortage protocol' to deal with serious national shortages of medicines?

CPS supports this change in legislation and the principle behind it. We have previously suggested that this type of responsibility should be part of a community pharmacist's professional practice working closely with other prescribers of medicines. The fragile nature of the supply chain has been highlighted in the past year in terms of shortages of generics and other medicines, e.g Epipens, and this type of responsibility would allow for greater flexibility in these examples which have already had a real impact.

How specific will the protocols be? The line 'clearly indicate what alternative can be dispensed and to which patients it applies' in terms of the alternative referenced here will this be from a suite of therapeutic alternatives or will this be determined specifically through the protocol? Clarity on the specificity of the potential protocol(s) would be appreciated.

The two paragraphs below may be more in the details of the implementation of the regulations but are potentially areas that should be considered.

There also has to be a consideration of going 'off label' or 'off license', will this be allowed through any new protocol and, if so, will this be stated? This may be required to support patients in even more extreme scenarios.

Also, what guidance would be available in the event of a serious shortage affecting patients where there is no obvious therapeutic alternative or form. The communication to the public and healthcare professionals needs to be clear in these circumstances to allow effective rationing and potential pooling of stock within the system.

Finally, there would be a significant issue with not being able to see the patient's records, as the pharmacist would be in the position of needing to use their professional judgement on medical substitutes without a full understanding of the patient's condition or whether certain therapeutic alternatives would be appropriate or not.

2. Do you agree with the introduction of a regulation making power in relation to serious shortages in case of a 'no deal' Brexit?

This makes sense to enable use of the legislation if a 'no deal' scenario comes to pass.

3. Do you have views on the principles outlined above, which are informing our assessment of impacts?

The most important factor in times of a serious shortage is access for individual patients to the medication they need. In these instances, it is part of a healthcare professionals' duty of care to put the patient first and do what they can to support them. It is challenging to quantify the impact on pharmacists and GPs, however pharmacy teams are already spending large chunks of their time sourcing products for patients within the current supply chain.

If this situation were to worsen then any measure or protocol to support this supply process would be welcome to allow patient facing care to continue for both pharmacists and GPs, who want to reduce these instances of liaising unnecessarily and spending time sorting these issues to a minimum.

We have been liaising with Scottish Government to ensure the Scottish Drug Tariff arrangements are robust enough to support contractors cashflow in terms of the adjusted prices north of the border. It is not known at this time what the financial impact will be (if any) for both parties and this will be monitored through our regular monitoring arrangements.

4. Do you have comments on the draft provisions?

N/A