

MHRA anti-counterfeiting proposals are fundamentally flawed and should be suspended pending a judicial review of existing laws.

New proposals in the Medicines and Healthcare products Regulatory Agency (MHRA) MLX365 consultation create an uneven playing field between independent and corporate pharmacies, says Rxchange, the online pharmacy stock exchange. The plans to restrict inter pharmacy trade are anti-competitive and will compromise patient care. They rely on interpretation of longstanding EU law*, which the MHRA believe the UK to have been in breach of for many years, to justify their position. As a final act of madness and prior to being disbanded in April 2010, the Royal Pharmaceutical Society of Great Britain (RPSGB) appears to have endorsed these proposals supporting the sacrifice of independent pharmacy in favour of corporate pharmacy and manufacturer' interests.

In a consultation paper slipped out over the Christmas holiday period, the regulatory authority propose to outlaw inter pharmacy stock exchange in the absence of a Wholesale Dealer licence (WDL), sending the industry into further turmoil at a time of unprecedented stock shortages and when pharmacy operating profits have never been under greater pressure. Coupled with imminent changes to the pharmacy regulatory framework the timing could not be worse. The proposals would add to the cost and administrative burden on independent pharmacies while putting no such caveat on corporate pharmacy branches. Independent pharmacies are no more able to withstand this assault than highly organised corporates. The objective is to reduce the risk of counterfeit drugs entering the medicines supply chain say the MHRA, but few involved in the last round of consultation buy their arguments. Objections were raised by hospitals, independent wholesalers, pharmacies and Strategic Health Authorities (SHA) but have been disregarded in favour of pandering to the profit protection wiles of global manufacturers, such as those the MHRA has associated with recently for their advertising campaigns.

It seems difficult to see how the consultation proposals will not be adopted, given the manner in which the consultation has been conducted and in the absence of judicial review. The proposals demand that all independent community pharmacies hold a Wholesale Dealer Licence (WDL) in order to trade stock with another pharmacy, irrespective of the size of their operation. Currently inter pharmacy trade is permitted under existing UK law and is used extensively to address difficulties resulting from stock shortages and the imposition of manufacturer quotas, to meet day to day prescription requirements. The MHRA also intend to remove a discounted WDL option, whilst allowing the largest corporate pharmacy groups to transfer or exchange stock at will and under no such restriction.

The consultation claims that the current practise of stock exchange by pharmacies under Section 10.7 of the Medicines Act 1968 is in breach of EU legislation*, but the document excludes any assessment of the legal implications, has taken no judicial review of the existing EU and UK legislation, ignores the exemptions the legislation allows for and takes no consideration of the significantly different commercial operating of the UK pharmacy market. Accordingly, the new proposals could fall far short of EU legislative guidelines and could result in an anticompetitive and therefore unlawful new set of guidelines.

Rxchange Commercial Director, Chris Wood said: *“Article 77 of the EU document stipulates that those engaging in wholesale activity should be subject to ‘possession of authorization’. Our belief is that the current exemption under Section 10.7 gives this in conjunction with the existing registration requirements and inspection of pharmacists and pharmacies by the RPSGB. Any attempt to waiver exemption under Section 10.7 by the MHRA – unless under the provisions of an instruction following judicial review – would be unlawful under EU law, as determined in the opening paragraphs of the Directive where it states ‘ this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the community’. On whatever scale ‘the community’ is interpreted, be that European or UK.”*

Further, the consultation’s Impact Assessment selectively quotes figures provided by Rxchange Ltd. in their previous detailed response to the 2008/2009 consultation document, but omits significant evidential pieces of information that would alter the stated impact. The document appears entirely self-serving and there only to maintain apparent confidence in the MHRA as a regulator. The claims to protect public health are very poorly evidenced. The proposals are a knee-jerk reaction which are disproportionate to the evidenced scale of the problem and lacking quantifiable measures for the improvements the proposed guidelines claim they will deliver.

“We feel the Health Minister has been misled into supporting these proposals, by claims of a complete, thorough and inclusive Impact Assessment, but the evidence suggests otherwise. It’s political posturing, especially since healthcare and the value we get for healthcare is likely to be at the heart of the election debate this year. If the changes to Section 10.7 are implemented, the result will be more shortages, more waste, but no less counterfeit stock entering the supply chain – I call that lose, lose. The MHRA need to suspend the consultation and ask the courts for a definitive legal interpretation before changes are made to existing UK laws.” commented Chris Wood.

The consultation process is itself drawing criticism, following an equally problematic process started in December 2008, which had to be extended, and the forum following only met in October 2009 despite a stated timeline of conclusions for Spring 2009.

The latest consultation procedural anomalies include omitting the distribution list while asking for recipients to forward to others that haven't received the document, a tacit admission of the distribution failings. They also failed to consult registered interested parties who have responded to the initial consultation and subsequently met with the MHRA. This indicates strongly that they are looking for a very narrow consultation channel and to dismiss out of hand any previously registered objections.

This consultation has set a time-line of just 84 days with implementation to commence in April 2010, suggesting that the outcome is already assumed and planning is underway. By anybody’s standards, flying in the face of an apparently open consultation process.

*Directive 2001/83/EC

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Rxchange is a secure online marketplace for UK registered pharmacies to trade stock and provides a 'Direct to Pharmacy' channel for wholesalers and manufacturers. Rxchange enables pharmacies to manage their stock better, smooths difficulties in the supply chain and significantly reduces stock wastage.