



THE PHARMACISTS STOCK MARKET

Rxchange response to MHRA document MLX 365

**'Consultation on measures to strengthen the
medicines' supply chain and reduce the risk from
counterfeit medicines'**

Document prepared for:

MHRA

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Introduction

Rxchange welcomes the opportunity to comment on the document MLX365. Before discussing the proposals in detail, we would like to make clear that Rxchange accepts that every reasonable step should be taken to eradicate the possibility of entry of counterfeit stock to the legitimate supply chain.

Rxchange provides a secure on-line B2B service for UK pharmacies to locate hard to obtain pharmacy stock and redistribute viable pharmacy stock to other pharmacy locations. The system reduces waste and smoothes supply difficulties.

Last year we made an exhaustive response to the initial consultation MLX 357. We consider that the issues and objections raised in that response still stand and refer you to that document for background and financial information.

(<http://www.rxchange.co.uk/press/Rxchange-response-to-MHRA-MLX357-110309.pdf>)

We have also recently raised serious concerns over the process followed during the launch of the current consultation. We have included the documentation for this in Appendix A. We have included the MHRA's response in Appendix B.

Our response to the proposals for Pharmacies (41-52)

1. The proposals are anti-competitive under EU law. They allow corporate pharmacies to continue to make strategic economic decisions about stock management, while independent pharmacies will have no such ability. Put simply, not only can they buy at better prices, but the corporate can hold larger stocks and manage its waste reduction through inter branch transfer. These are privileges that will not be available to independent pharmacies.
2. The proposals are not 'in the spirit' of EU Directive 2001/83/EC which seeks, for example, '...to safeguard public health. However 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'. The Directive also acknowledges the standing of member states national law.
3. The proposals are no longer based on analysis of the UK pharmacy-to-pharmacy marketplace (as originally proposed and widely endorsed by last years respondents) but based on a unilateral interpretation of EU law. This interpretation is stated as fact - that changes to existing UK legislation *must* be made to comply with existing EU law. This seems very fortuitous timing. If this is truly a 'non-conformance', then the UK has been in breach of this law since 2001 and authoritative ethical documents – such as the Medicines, Ethics and Practice (MEP) have been fundamentally flawed since that date. Alternatively it is now being used to effect a specific outcome. We consider that the EU law is open to interpretation – it does not say that a WDL is required – it talks instead about 'authorisation to engage in activity as a wholesaler in medicinal products'. While acknowledging the MHRA's response to our previous correspondence over this issue (see appendix B) we consider there are flaws in the response and still consider that current legislation provides the required 'authorisation'. We reiterate that this is a point for the courts to make a definitive ruling on and that such far reaching changes to the national economic, commercial, environmental and healthcare operation should not be left to policy makers.

4. Current difficulties in the UK supply chain are well documented (and a concern to the government as identified at the recent government summit). To restrict inter-pharmacy trade compounds the problem at a time when obtaining medicines is proving ever more complicated, time consuming and costly.
5. Restricting transfer of stock to 'local exchange' is unlikely to satisfy patient demand as evidence suggests supply difficulties are often regionalized.
6. If the proposals are adopted there will be no mechanism to source or locate stock from across the UK and there will be no method to allow pharmacies to release unwanted stock. We must assume that as commercial operating costs continue to grow, savings will be made by reductions in stock holding. Patient healthcare will suffer. This is in direct conflict with existing ethical guidelines and the EU directive.
7. There will be no mechanism to locate emergency stock other than by phoning a neighbouring pharmacy. This is a backward step in both healthcare and commercial terms.
8. There is no consideration of the financial or environmental costs of disposing of unused stock.

Our response to the proposal to remove £35,000 turnover concession (18)

If the Section 10.7 exemption is removed we propose that the reduced fee concession is maintained. Alternatively, a cost effective authorisation should be introduced that can only be held by registered pharmacies. This would at least allow them to fulfil existing obligations to provide other health providers with stock (GP's, Mental Health trusts etc)

APPENDIX A: Process Objection

Mr Martin Bagwell

MHRA Consultation Coordinator
Room 16th floor
Market Towers
1 Nine Elms Lane
LONDON SW8 5NQ

8 February 2010

Dear Mr Bagwell

MLX 365 OBJECTION

We would like to raise formal objection to the Consultation MLX365 and believe that the consultation is so fundamentally flawed that it should be suspended immediately. We consider that there are a raft of procedural anomalies and serious flaws in your processes and that there is a flagrant disregard for UK and EU law.

We consider that due diligence has not been undertaken, the process contravenes the legal governance of consultation and is directly contrary to Government "Better Regulation Principles". The five principles of good regulation state that any regulation should be:

- transparent
- accountable
- proportionate
- consistent
- targeted – only at cases where action is needed

The consultations proposals are fundamentally anti-competitive making them contrary to European trade regulation and on this point alone are therefore unlawful.

In our opinion the consultation document makes misleading, un-tested and consequently, in our view, unlawful conclusions about the exemptions already in place under EU law governing inter-pharmacy trade.

1). Our objections to the consultation process are as follows, and these alone require the immediate suspension of the consultation pending review:

- I. Once again, and despite our formal objections to this modus operandi used in the previous consultation (MLX357) on this topic, the consultation paper has been 'slipped out' over the Christmas holiday and apparently distributed to only a narrow band of non-independent pharmacy contacts.
- II. The latest consultation pack has serious procedural anomalies including missing Annex C (which would confirm the circulation list), asks recipients to forward to others that haven't received the document – a tacit admission of the distribution failings - and the failure to consult registered interested parties who have responded to previous consultation and met with the MHRA. This suggests that the MHRA are looking for a very narrow consultation channel and therefore a deliberate act on behalf of the MHRA to exclude interested parties from the consultation – making the process unlawful.
- III. Your introduction statement suggesting that the proposals will increase protection from the risk of counterfeit medicines reaching patients in the UK is prejudicial to

the remainder of the document, at no point is the scale of the 'problem' evidenced, quantified or validated.

- IV. You acknowledge the breadth of the interested parties & stakeholders in the industry but again we feel that you have excluded them by design from the consultation. This contravenes the Government Code of Practice, which requires that **"the consultation exercise is accessible to, and clearly targeted at, those people the exercise is intended to reach."** Clearly, either you did not intend it to reach all these stakeholders, which is a contravention of the principles, or your process has failed to consult them fully.
 - V. Further, we consider that the time-line for the consultation is wholly unrealistic – 84 days from start-to-finish a break-neck consultation process by any standards, even if the document was complete, distributed appropriately, and not released over the busiest trading period of many stakeholders & extensive holiday period of Christmas. Such a process risks a procedural suggestion that the outcome is already assumed and planning is underway. This is a direct contravention of the Government Code of Practice, **"consult at a stage when there is scope to influence policy outcome"**.
 - VI. You claim that you can meet the timeline on the basis of consultation to-date (not evidenced) in spite of an Impact Assessment which is also fundamentally flawed and the fact that the forum following MLX357 only met in October 2009 despite a stated timeline of conclusions for Spring 2009. Respondents to the previous consultation report that they still have outstanding queries with the MHRA that have not received responses.
 - VII. The Impact Assessment includes selectively quoted market assessment data provided by Rxchange Ltd. in their previous detailed response to the 2008 consultation document, but omits significant evidential pieces of information that would alter the stated Impact Assessment, and fails to acknowledge the source of the data.
- 2). Our objection to the MHRA's interpretation of the applicable law in steering the proposed consultation are as follows:
- I. We believe that your interpretation and attempted application of EU law in support of your proposals is erroneous, untested and would be unlawful if adopted.
 - II. The consultation suggests that current UK practises are in breach of EU legislation, but the document includes no assessment of the legal implications, has taken no judicial review of the legislation, ignores the exemptions the legislation allows for, makes no consideration of different territory requirements and takes no account of the significantly different commercial operating of the UK pharmacy market.
 - III. Further in the absence of a legal interpretation, to press forward with such proposals could put UK pharmacy in contravention of EU law, since neither the MHRA, RPSGB nor indeed the Health Minister are qualified to interpret EU law definitively.
 - IV. The applicable EU law which is used as a justification for the proposed changes in the consultation appears to be significantly misquoted, since by providing the legislation in an incomplete form the meaning is lost. The Consultation references

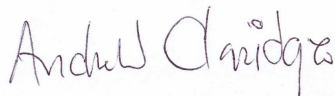
only Articles 77 and 78, whereas we believe that the document should be considered as a whole for it to be taken in context (especially points 2 - 6) in order to fully understand the objectives of the legislation. Further, consistently, the MHRA proposals and consultations have suggested that the EU legislation allows only for 'occasional, small quantity and not for profit' exchange, but this statement is not stated or inferred in the Directive, suggesting the MHRA are adopting a deliberately misleading stance, or could be privy to additional information that they have not referenced or made public.

The current proposals have dismissed out of hand the objections and comments by a variety of bodies and stakeholders during the previous consultation, but adopt strongly the position put forward by global pharma. One has to question the impartiality of the process when the MHRA are actively involved with particular manufacturers in the funding of anti-counterfeiting advertising campaigns.

- V. We believe that your interpretation of EU law in the document is in any case mistaken or has been deliberately misrepresented to satisfy political requirements.
 - a. Article 77 (1) stipulates that those engaging in wholesale activity should be subject to 'possession of an authorization' - our understanding is that the current exemption under Section 10.7 of the Medicines Act 1968 gives this alongside the requirement for pharmacists to be accredited and registered with the RPSGB, as well as all pharmacies being registered pharmacy premises, subject to inspection and under the supervision of a Responsible Pharmacist during all trading hours. At no point does the directive state that a Wholesaler Dealer Licence is required - stated as fact in MLX 365.
- VI. Any attempt to waiver Section 10.7 by the MHRA – unless under the provisions of an instruction following legal interpretation in the courts – we believe is unlawful under UK and EU law.
- VII. UK inter-pharmacy exchange of stock is not only permissible under the legislation, but Article 80 makes express endorsement for it.

We look forward to your urgent attention and confirmation that the consultation has been suspended. As the issues raised here are not specific to 'strengthening the medicines supply chain' OR 'reducing the risks from counterfeit medicines' but relate to interpretation of existing UK and EU law we insist that you urgently take this matter to Judicial Review for a definitive clarification of the applicable laws.

Yours faithfully



ANDREW CLARIDGE
Rxchange Ltd.

Appendix B: Process Objection - MHRA Response

Mr Andrew Claridge
Rxchange Ltd.
The Old Kings Arms
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Colchester
CO7 6JN
22 February, 2010

Re: MLX 365 OBJECTION

1. Thank you for your letter dated 8 February 2010. The issues you raise fall into two areas – procedural elements to do with the conduct of the consultation itself, and issues to do with the content of the consultation. As Consultation Coordinator, I am chiefly concerned with the procedural aspects of MLX 365, but have liaised with colleagues to answer your concerns about the content of the consultation. I also attach a copy of the Code of Practice on Consultation for your reference.

Procedural aspects of MLX 365

2. Firstly, you raise concerns about the timing of the consultation. The Code of Practice states that all government consultations should last for a minimum of 12 weeks¹, or 84 days. However, I note your concern regarding the time at which the consultation was started, as the Christmas and New Year period can be a very busy time for many businesses. For this reason we have now decided to extend the consultation period for MLX 365 by two weeks.² A note to this effect will be placed on the MHRA's website.

3. You also comment that the circulation list for the consultation seemed to be limited and for this reason MLX 365 was not properly targeted. We acknowledge that the List of Consultees (Annex C) was not included when the consultation was first posted, but was added to the webpage on 4 February 2010. You will see from this list that over 3,500 organisations and individuals were notified by post during the consultation process, and further stakeholders were alerted by our online alert notification system. Under the MHRA's current consultation procedure we only have to notify consultations by email, but in this case we decided to send alert postcards by post for MLX 365 as well, because of the particular importance of this consultation to a number of stakeholders. It is also standard practice for the MHRA to ask recipients to forward on our consultations to other interested parties. This ensures that it reaches the widest possible audience.

4. Rxchange was not contacted directly when MLX 365 was posted and this was an oversight on our part. However, you did attend a meeting at the MHRA on 20 October 2009 at which the issue of particular concern to you was discussed in detail. The MHRA invited those who attended that meeting to give thought to the issues raised and to respond to the second consultation when it was published later in that year. We do not therefore accept that we have excluded anyone from the consultation process, as you suggest.

5. In terms of the likely timing for implementation of the measures proposed in the consultation, the MHRA will take stock of all the comments received during the consultation period, review the proposals in the light of comments received and determine a timetable for those that will move forward to implementation. It is now unlikely that we will be in a position to implement key areas of our proposals by the proposed April 2010 date.

6. As we have done with the responses to our initial consultation on these topics, we will publish the responses we receive (unless asked by the author not to do so) and provide a commentary on them.

Content of Consultation MLX 365

7. You suggest that we have not evidenced the scale of the problem that our consultation proposals are intended to address. However, you will be aware that this consultation followed a preliminary consultation (MLX 357) which set out clearly the problems that this initiative is intended to address, and MLX 357 was referenced in the current consultation document and remains available on MHRA's website, together with responses received and our commentary on them. We have also published an updated Impact Assessment on our revised proposals.

8. We used data supplied by Rxchange in response to MLX 357 in our impact assessment³ because we felt that it would give an idea of the costs to industry of the measures that we were proposing. If Rxchange would like to be added as a source for this data, we would be happy to modify the Impact Assessment.

9. Your main stated concern on the content of MLX 365 is our interpretation of EU law. You state that the exemptions under section 10(7) of the Medicines Act are compatible with European law, and that our proposed amendment to the existing 10(7) exemption is unlawful under UK and EU law.

10. The MHRA disagrees with your interpretation of this exemption. Throughout this process we have consulted legal advisers on the proper interpretation of EU legislation and in particular the provisions in Article 77 of Directive 2001/83/EC. You suggest in your letter that the current Article 77(1) stipulates that those engaging in wholesale activity should be subject to 'possession of an authorization', yet omit the rest of the sentence. The complete text of Article 77(1) states that: *"Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorization to engage in activity as a wholesaler in medicinal products, stating the place for which it is valid."*

Furthermore, Article 77(2) goes on to say:

"Where persons authorized or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the authorization provided for in Paragraph 1."

Ultimately the definitive interpretation of the law is a matter for the courts to determine. However we believe that the wording in Article 77(2) leaves no room for doubt that persons authorised or entitled to supply medicinal products to the public (such as community and hospital pharmacists) who engage in wholesale distribution must also hold the authorisation to engage in that activity.

European law defines wholesale distribution of medicinal products as:

"All activities of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned."

11. You also cite Article 80 of Directive 2001/83/EC as giving express endorsement to inter-pharmacy exchange of stock (without the need for a wholesale dealers licence). I am not clear how that conclusion is reached, as the opening sentence of Article 80 begins with the words "Holders of the distribution authorisation must fulfil the following minimum requirements". So one could safely conclude that Article 80 does not relate to anyone not holding a distribution authorisation (i.e. a pharmacy without a wholesale dealer licence). Article 80 most certainly does not allow inter-pharmacy exchange of stock between two pharmacies neither of which holds a wholesale dealers licence.

12. As you know, European Directives are brought into law in Member States by transposing the provisions into national legislation. The UK's Medicines Act 1968 pre-dates much of the EU legislation, and over the years many provisions within the Medicines Act have been superseded by EU law. In respect of section 10(7) of the Medicines Act and associated schedules which currently provides the exemption that has allowed an amount of trading of medicines by pharmacists without wholesale dealers' licences, this was superseded by the provision now contained in Article 77 of Directive 2001/83/EC. The provisions now contained in Article 77 of the Directive have superseded an earlier Directive that contained the same provision.

13. Having identified the inconsistency between section 10(7) of the Medicines Act 1968 and Article 77(2) of the 2001/83/EC Directive the MHRA needs to take steps to align UK provisions

with EU law. In considering the most appropriate way to do so we have taken into account the need to ensure that pharmacists can continue to meet patients' needs when, for example, they do not hold in stock a medicine that a patient needs urgently. In these circumstances we will permit exchange between pharmacy businesses of small quantities of a medicine to meet the need of the patient as long as that exchange is not for profit. Any more extensive business to business transactions will require a community pharmacist to hold a wholesale dealer's licence, and to comply with all the requirements associated with that licence.

14. Finally, you asked that we take the matter of section 10(7) to Judicial Review. I am not clear what exactly you envisage in this regard. Briefly, such action is ordinarily concerned with ensuring that actions of public bodies, including the executive, are lawful. Ultimately it is for the courts to determine what the law permits or demands. The courts undertake this task by interpreting the relevant legislation and by applying and developing the common law. For the reasons set out in this letter we do not believe that the MHRA has acted unlawfully or in an unreasonable manner in its use of the formal procedures or discretionary powers that are available to it. It is of course a matter for others outside the MHRA to consider whether they wish to challenge the MHRA's actions in the courts.

15. This letter does not of course prejudice your right to respond officially to MLX 365, and we would encourage you to send in your views in response to this consultation. If you have any further concerns about the procedural aspects of this consultation, please feel free to contact me. All content queries should otherwise be forwarded to the MLX365 response inbox; MLX365@mhra.gsi.gov.uk

Yours sincerely,
Mr Martin Bagwell
MHRA Consultation Coordinator