



THE PHARMACISTS STOCK MARKET

Rxchange response to MHRA document MLX 357 'Consultation on measures to strengthen the medicines' supply chain and reduce the risk from counterfeit medicines'

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Introduction

Introduction

Rxchange welcomes the opportunity to comment on the document MLX357. 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.

Rxchange was launched in 2007 (following 2 years extensive development) to support community pharmacy, not as an explicitly commercial proposition but to assist a depressed sector of the healthcare market. We believe that our systems positively promote – through control and audit – the legitimate redistribution of pharmacy stock.

A detailed description of Rxchange can be found in Appendix A

Because of the experience we have in the pharmacy-to-pharmacy market place we would request a meeting with the MHRA to discuss these proposals in detail.

Please note: In this response document we have used the typographical format (Pnumber) to reference the paragraph number in the proposal document and shown the abridged text and questions in grey.

Detailed response

Detailed response to MLX 357 Annex A

Proposals for changes to the supply chain

With reference to the following points in the document:

P25. Bring all operators up to the standard of the best Rxchange endorses this proposal.

P26 Proposals meet the Better Regulation objectives

Rxchange opposes this suggestion since the proposals seem to be directly contrary to Government "Better Regulation Principles" (BRE) The five principles of good regulation state that any regulation should be:

- **Transparent** – The proposals and the nature of the consultation do not meet any definition of transparency, since, significant tracts of the industry the proposals intend to regulate have not been actively engaged in the consultation and the proposals do not clearly illustrate the potential far-reaching impact they will have, if adopted
- **Accountable** – There are no defined measures of success or consideration as to how the proposals could be achieved
- **Proportionate** – The proposals are biased and reactionary. They do not consider the commercial issues and, in particular, the impact they will have on small pharmacy businesses at a time of world recession and financial hardship. They are **not** proportionate to the specified risk
- **Consistent** – There seems disparity between what independent and corporates will be able to do. They disadvantage around one third of the industry (i.e. independent pharmacy). Therefore the proposals are not fair or equitable
- **Targeted** – This is more of a scatter gun approach

P27. There will be a reduction in numbers of businesses operating in this sector.

Rxchange would like to see more information on this – numbers, time-scale, cost implications, employment implications. We would like to understand how supply will be maintained during this "reduction" and the implications to patient health care?

Wholesale dealers

PROPOSALS

Require an applicant for a Wholesale Dealer's Licence to demonstrate that he/she is a "fit and proper person" to undertake such a role, with minimum requirements to be set out in guidance;

Rxchange agrees in principle

- Require disclosure by applicants of criminal records;
Rxchange agrees in principle

- Empower MHRA to decline a Wholesale Dealer’s Licence if an applicant discloses a relevant criminal conviction;
Rxchange agrees in principle, but feel that this proposal will be very easy for a company to sidestep by simply ensuring that the named applicant has a clean record (while others with controlling interests in the company may not).
- Require payment in advance of fees for the licence and for inspection;
Will this be a sliding scale of fees? If pharmacies require a licence to sell their surplus retail stock they should not have to pay the same as a full time wholesaler.
- Introduce a “due diligence” obligation into the legislation, with a requirement to notify the MHRA of suspicious events;
Rxchange agrees in principle but we are unsure how this will be audited and enforced. What is the penalty for non-compliance?
- Introduce a requirement that each “body corporate” at a Wholesale Dealer’s site must have its own Wholesale Dealer’s Licence which cannot be transferred to another part of the business;
Rxchange agrees in principle. However, what will happen to availability (and therefore patient healthcare) if a large wholesaler is forced to temporarily cease trading because of a non-compliance in one part of the organisation. How quickly could the WDL be amended? How will this “amending” process be administered and not abused?
- Clarify MHRA powers to refuse to grant/suspend/revoke Wholesale Dealers’ Licences if service fees or other fees are not paid;
Rxchange agrees in principle
- Remove the £35,000 turnover concession regarding reduced fees.
Rxchange opposes this proposal. This would adversely affect smaller retail pharmacies that hold a WDL

Q. In the light of the increasing threat from counterfeit medicines in the supply chain do you think that these proposals are proportionate and appropriate?

Please see the specific answers above.

Additionally Rxchange believes that the issue of counterfeit drugs entering the market is over-stated in the consultation document’s initial pages, and is not supported or quantified evidentially:

- In the light of ‘increasing’ threat from counterfeit medicines – this is not quantified and the figures quoted (9 cases) are only for the period 2004-7. There is no supporting evidence for 2007-date, there is no trend analysis or suggestion of how cases are currently being detected
- It is not clear what proportion of UK pharmaceutical stock movement detected counterfeit stock accounts for. How many units, what is the NIC value? i.e. What proportion of £10.2B stock delivered to patients through community pharmacies is received into the supply chain as counterfeit stock?
- How are these counterfeit products being produced? – Rxchange believe very robust actions should be taken, at source, to ensure counterfeit stock is not produced and infiltrates the supply chain at the highest levels.

Q. Do you have suggestions as to other measures in the wholesale dealing area that the MHRA should consider introducing within the current EU framework?

Some of the manufacturers of these products used holograms as an easy and quick way of identifying genuine products. These are highly effective and – relative to the value of the inventory – an inexpensive protection measure. If manufacturers are really concerned with dealing with the issue of counterfeit stock then they should identify their stock into smaller groups. Presently they are divided into batch or lot number. There could be thousands of boxes within each batch. If they were to make batches of 10,000 then have these subdivided into lots of 1000's with each lot going to a specified wholesaler, there would be greater traceability of the item. All pharmacists could then check to see which wholesaler their item originated from. This tied in with the hologram would increase security and safety.

Q. What, in your view, would represent appropriate “due diligence” requirements to place on Wholesale Dealer Licence holders?

Rxchange does not consider itself qualified to comment.

Q. Do you have any concerns that these measures could adversely impact on public health – please provide an explanation of your concerns?

Any form of expensive, timeconsuming over-regulation risks overloading (or shutting down) the WDL holder. This has the potential for disrupting the supply chain to a more significant level than a potential 1% of counterfeit stock

Q. It would be very helpful if you could quantify any assessment of the impact of these proposals, as well as providing information about the type, and size of organization that will be affected (eg whether the impact relates to, say, a large multi-national organisation, a small or medium-sized enterprise (SME) or healthcare provider). It would be helpful if your assessment were to include, but not be restricted to, the financial impact of these proposals.

Rxchange does not consider itself qualified to comment.

Responsible persons

Responsible persons

PROPOSALS

- Minimum qualifications for RPs ;
- Require membership of a professional body;
- Introduce a Code of Practice against which RP performance can be judged;
- Establish a register of RPs to be maintained by the MHRA to include personal details, appointments and the results of vetting (eg by requiring applicants for RP status to declare any criminal convictions);
- Require continuous presence of an RP during business hours at each site;
- Require RP deputies to be qualified RPs;
- Introduce a “due diligence” obligation into the legislation and a requirement to notify suspicious events;
- Require each site of a multi-site wholesaler to nominate an RP.

Q. In the light of the increasing threat from counterfeit medicines in the supply chain do you think that these proposals are proportionate and appropriate?

Rxchange agrees in principle, although we are unsure how “due diligence” obligations will be audited or upheld

Q. Do you have suggestions as to other measures to strengthen the regime in respect of RPs that the MHRA could introduce within the current EU framework?

Rxchange does not consider itself qualified to comment.

Q. What issues would you expect to see covered in a Code of Practice for RPs?

Rxchange does not consider itself qualified to comment.

Q. What, in your view, would represent appropriate “due diligence” requirements to place on an RP?

Rxchange does not consider itself qualified to comment.

Q. Do you have any concerns that these measures could adversely impact on public health – please explain your concerns?

Rxchange does not consider itself qualified to comment.

Q. Do you have a view on what would represent a suitable minimum level of qualification for an RP, and what professional bodies would be appropriate?

Rxchange does not consider itself qualified to comment.

Q. It would be very helpful if you could quantify any assessment of the impact of these proposals, as well as providing information about the type, and size of organization that will be affected (eg whether the impact relates to, say, a large multi-national organisation, an SME or healthcare provider). It would be helpful if your assessment were to

include, but not be restricted to, the financial impact of these proposals.

Rxchange does not consider itself qualified to comment.

Medicines imported into the UK for export only

Medicines imported into the UK for export only

PROPOSALS

Ensure that operators importing medicines that are to be exported to 3rd countries are required to check the authenticity and provenance of the medicines they buy and keep records of all transactions;

Rxchange endorses this proposal. .

Stop short of applying all regulatory requirements (such as batch testing) to businesses trading only in medicines that are imported for export to 3rd countries;

Rxchange endorses this proposal.

Ensure that the regulatory authority (MHRA) has the authority to inspect the premises and records of businesses conducting “import for export” trade, including sample testing of products, if deemed necessary.

Rxchange endorses this proposal.

Q. In the light of the increasing threat from counterfeit medicines in the supply chain do you think that these proposals are proportionate and appropriate?

Please see our comments above

Q. Do you have suggestions as to other measures to strengthen the regime governing import for export of medicines that the MHRA could introduce within the current EU framework?

Rxchange does not consider itself qualified to comment.

Q. Do you have any concerns that these measures could adversely impact on public health – please explain your concerns?

Rxchange does not consider itself qualified to comment.

Q. It would be very helpful if you could quantify any assessment of the impact of these proposals, as well as providing information about the type, and size of organization that will be affected (eg whether the impact relates to, say, a large multi-national organisation, an SME or healthcare provider). It would be helpful if your assessment were to include, but not be restricted to, the financial impact of these proposals.

Rxchange does not consider itself qualified to comment.

Storage and Transit of Medicines

Storage and Transit of Medicines

PROPOSALS

- Licence logistics providers as compliant with Good Distribution Practice standards. Storage sites could be licensed in their own right or named on the relevant licences;
 - Establish powers to inspect logistics providers “for cause”;
 - Possible but would think there is suitable legislation in place
- Place a legal obligation on persons contracting for transport and storage to ensure the probity of those with whom they contract;
- Introduce legislation that requires contract givers to audit transport suppliers and to make audit reports available for review by inspectors;
 - Introduce legislation that requires all trans-shipment/logistic providers/freight forwarders etc to be named on the main Wholesale Dealer’s licence, together with activities taking place at that location. No other site to be used by the wholesaler.

Q. In the light of the increasing threat from counterfeit medicines in the supply chain do you think that these proposals are proportionate and appropriate?

Rxchange does not consider the proposals appropriate. Regulating and auditing logistics providers would be very difficult and expensive.

Q. Do you have suggestions as to other measures to strengthen the regime governing transportation and storage of medicines that the MHRA could introduce within the current EU framework?

Logistics companies should have the option of registering for a “charter mark” which would show that they comply to a standard procedure, but this should not be mandatory.

Awarding this charter may be subject to on-site inspection and audit. Wholesalers should have the option to choose, if they prefer, to use accredited carriers or not. The important issue is to ensure there is an audit trail for the goods which leads to the logistics company and an auditable trail after the goods are received. If the goods are later found to be compromised the first point for consideration should be the logistics company. It is therefore in their interest to comply with the Charter guidelines. It may be appropriate to inspect providers for “cause”, but existing legislation should suffice.

To assist in the audit trail, shipments could carry a tamperproof seal with the originators ID. The receiver could then reject the delivery if this seal was broken or did not match the distribution documentation.

Q. Do you have any concerns that these measures could adversely impact on public health – please explain your concerns?

If you regulate the logistics companies then some of them would decide not to carry pharmaceuticals. This has the potential to restrict the movement and therefore availability of medicines. It would also drive up the costs of

transporting the goods increasing the gross price. This has the potential to negatively affect patient health care and drive up costs to the NHS.

Q. It would be very helpful if you could quantify any assessment of the impact of these proposals, as well as providing information about the type, and size of organization that will be affected (eg whether the impact relates to, say, a large multi-national organisation, an SME or healthcare provider). It would be helpful if your assessment were to include, but not be restricted to, the financial impact of these proposals.

Rxchange does not consider itself qualified to comment.

Pharmacies

Pharmacies

With reference to the following points in the document:

P54 [Pharmacists also trade] part packs and packs without original packaging/containers.

This is not permitted under the latest MEP guidelines and including this in this consultation confuses. This is no longer an issue. (The Rxchange stock exchange website does not facilitate such a trade).

P55 There is a requirement for the pharmacist engaged in inter-pharmacy trade to keep copies of requisition orders for 2 years, but there is no obligation to publish this data, no central collection of data and therefore no clear idea of the scale of this trade.

Rxchange provides an auditable route for this information

P56 there needs to be some strengthening of the rules governing the ways in which the Section 10(7) exemption is operating, to limit its potential for infiltration by counterfeit medicines.

The implication of this proposal is that (some) pharmacists are not to be trusted. If this is the case, it is hard to see how this route is more vulnerable than, for example, a pharmacist knowingly selling counterfeit stock over the counter.

In actual fact, using Rxchange actually provides a significantly more robust audit route for stock as the buyer and seller are both validated before they may use the system. The description (particularly the expiry information) is clearly specified as part of the sale and the invoice and delivery notes clearly record the product information. Users must also declare that the stock they are offering meets certain requirements. This declaration is auditable and enforceable.

This type of declaration is not made when selling “across the counter” to a member of the public. Inter-pharmacy transfers, on the other hand, are received by experienced healthcare professionals that will be aware of “inconsistencies” in any product they have received.

P56 confuses two channels of distribution. The proposals blur, or consider as interchangeable, B2B (business-to-business) and B2C (business-to-consumer) channels. This is a fundamental error - they are quite distinct. Any proposals need to be clear about this distinction and account for both channels accordingly. Section 10(7) relates to pharmacy-to-pharmacy business (B2B), where Rxchange operates. However, internet pharmacy is a B2C channel and Rxchange would agree that this channel could be more vulnerable to abuse and “present opportunities to dispose of counterfeits and to engage in other unregulated and illegal activity”.

PROPOSALS

- Collect and analyse data on wholesale activity taking place under the Section 10(7) exemption with a view to identifying the scale of the market and to undertake an impact analysis on any changes to legislation governing wholesaling activity;

Although Rxchange is unclear how you will be able to collect the required data, we fully endorse the requirement for a full impact analysis of proposed changes to Section 10(7). The information we have received from our users suggests the impact would be very significant. You are invited to view some of the responses at: www.rxchange.co.uk/news/MHRA-propose-changes-to-inter-pharmacy-trade.php#comments.

A selection of the responses are included in Appendix B

- Depending on the outcome of the analysis, consider restricting use of the Section 10(7) exemption to emergencies, specifying that this must be limited to no more than 5% of the total retail trade in licensed medicinal products at the registered pharmacy, with record keeping and sanctions if the limit is breached other than for demonstrable public health reasons;
Rxchange opposes this proposal vehemently. Restricting Section 10(7) to emergencies is un-enforceable.

“Emergency supplies” are not qualified or quantified in the proposals, nor is there any description of how this will be upheld in the absence of audit or control. This is not providing better regulation – it is providing an unworkable solution devoid of effective regulation, completely opposing BRE guidelines.

The trade between pharmacies has always existed to meet patient requirements. Now economics, patient satisfaction, and the high cost of specialist drugs has made inter-pharmacy trade a business imperative. To regulate against this will only serve to encourage “informal” trade, when the reality (that we fully endorse) is that greater transparency and auditability is required.

At its core, Rxchange provides a robust and auditable documentation for all items transacted through the site as part of its’ standard reporting suite. This documentation is far in excess of that which pharmacies would have time to create to meet the adhoc record keeping that would be necessary to meet the audit requirements of this proposal. Therefore, if the proposal was implemented as suggested, either:

- emergency procurement would be avoided and patient healthcare suffers
- audit documentation is neglected - pharmacy suffers sanctions and counterfeit drugs could enter the supply chain anyway
- the pharmacy spends time on the documentation but patient healthcare suffers as waiting times increase, as a result of decreased revenues and increased work burden

Rxchange successfully de-localises the provision of emergency stock to meet both localised and regionalised demand. These proposals would return pharmacy to the days when you could only get emergency stock from other nearby pharmacies. Public healthcare would suffer and effectively generate a “postcode lottery”. The proposals deny the positive impact that technology can offer- contrary to government policy.

Although we accept the threshold could be formally set at 5% we believe measuring and auditing this will be unworkable unless there is a legal requirement for the business to specify these sales in their accounts. Again, this seems totally against BRE principles.

- Requiring pharmacies that wish to trade in larger quantities of medicines to hold a Wholesale Dealer's Licence and comply with all appropriate requirements;

This is an existing requirement and should not be in the proposals

- Strengthen standards on the safe disposal and exchange of unwanted and near expiry stock, to be regulated by RPSGB inspectors;

Rxchange endorse this in principle: The process must be as light-weight as possible. Rxchange is keen to discuss this with the MHRA

- Introduce standards for the disposal of unused and discarded packaging in pharmacies;

Rxchange endorse this in principle. This must be a simple process.

- Introduce targeted and risk-based inspections by RPSGB.

Rxchange believes that this is already provided for. Surely this is what the inspectors do already. Why is this in the proposals?

More importantly, how will this be funded and taken forward in 2010 when the structure of the regulatory and membership bodies will change and any increase in inspection should not be funded by the membership.

Q. In the light of the increasing threat from counterfeit medicines in the supply chain do you think that these proposals are proportionate and appropriate?

Rxchange does not believe so. Restricting Section 10(7) to emergencies or the idea of forcing all UK pharmacies wishing to trade pharmaceuticals with one another to obtain a WDL is unrealistic, overly burdensome, unnecessary and unlikely to reduce entry of counterfeit medicines into the supply chain.

Pharmacies are already suitable places to store pharmaceuticals and supply them to patients. They are regulated by the Medicines Act and are inspected by the RPSGB to ensure compliance to the regulations. The public should have as much trust in obtaining non-counterfeit medicines from a pharmacy as a proprietor of another pharmacy would in obtaining the same product from that pharmacy. The level of trade between pharmacies is insignificant compared to the amount occurring between WDL holders and pharmacies. Effects of reducing counterfeit medicines by regulation at the pharmacy-end would be proportionately ineffectual.

The proposals would be unlikely to eradicate the practise of stock exchange, but would remove the audit trail and controls and drive the practise into informal, underground exchange.

The proposal to close trade between registered pharmacies does not, looking at the evidence provided, reduce risk to patients.

Pharmacies are already 'licensed', registered, regulated and inspected. No evidence is provided to require more.

We support the proposal in principle (see comments above regarding measuring this) to formalise the limit on wholesale activity allowing the wholesale of inventory as a percentage of their turnover. The actual percentage should be determined following further investigation and not based on an "arbitrary" value that has never been tested by law or quantified.

Rxchange does not endorse any proposed requirement for the additional expense and regulation the requirement for a WDL would impose in an already hostile regulatory environment.

No evidence is provided that shows Section 10(7) has been the cause of counterfeit stock entering the market. Accordingly, it is the view of Rxchange that this proposal has a greater commercial benefit to the manufacturers and wholesalers (including the corporate pharmacy groups - see below), than reducing the risk of counterfeit stock entering the supply chain.

These proposals have the potential to create an unfair commercial advantage in favour of the corporate pharmacy groups - assuming they are able to continue to transfer their stock between branches. Independent pharmacies would have no such mechanism. The proposals would therefore remove a prudent and appropriate business management tool when the UK economy and UK pharmacies, in particular, need it most. This proposal, when considered alongside other financial pressures affecting pharmacies today, will make some smaller and remote pharmacies unviable – ultimately compromising patient healthcare.

Q. Do you have suggestions as to other measures the MHRA could introduce within the current EU framework to further protect pharmacies from the threat from counterfeit medicines?

Rxchange believes it would be far better to police and control entry of pharmaceuticals into the EU from known sources of counterfeiting countries. Greater expenditure on finding and fining counterfeiters would be a better use of resources than policing an already well regulated pharmacy sector. A pan-European mechanism of encoding product data into barcodes to enable tracing and reconciliation would be more effective. This should be made part of Good Distribution Practice. In this way, the source and movement through the supply chain could be traced as in the food industry.

The proposals fail to clarify the position with regard to

- Buying groups associated with dispensing doctors
- Co-operative buying groups
- Returns to suppliers/wholesalers for pharmacies without WDLs (for example, how will the MHRA proposals challenge the ability of unscrupulous practitioners 'forcing' unauthorised stock back into the network via wholesale returns?)

The proposals do not state the perceived risk or the intended risk reduction these proposals would have. Therefore:

- How will terminating inter-pharmacy trading prevent counterfeit stock entering the market?

- How will pharmacies having WDLs (therefore being further regulated) further protect public health and prevent counterfeit stock reaching the patient

A much more measured response and quantifiable method of improving the flow of stock in the UK is by establishing approved minimum standards and audit policies, requiring any inter-pharmacy trading of stock to use the approved process or suitably compliant systems provider. Rxchange would wish to contribute to any such process.

Q. Do you have any concerns that these measures could adversely impact on public health – please explain your concerns?

Currently pharmacies hold a large amount of stock on their shelves to satisfy patient demand. If they are not used it ends up being thrown away – at the pharmacies expense. With the current economic pressures it is likely that they will scale back the amount of stock held and therefore patients will not be able to obtain their medicines “on demand”.

Rxchange has worked hard over the past 2 years to make it easier for pharmacies to locate and purchase hard to obtain items and satisfy “owings”. (part fulfilled prescriptions that cannot be presented for reimbursement until complete). We are even aware that some members of the public have asked their pharmacy to use Rxchange to satisfy their prescriptions. This does not just enable fulfillment at local level – this can even-out supply problems across the UK. Restricting inter-pharmacy trade will destroy this lifeline as there will be no incentive for stockholders to list “emergency” stock.

Q. It would be very helpful if you could quantify any assessment of the impact of these proposals, as well as providing information about the type, and size of organization that will be affected (eg whether the impact relates to, say, a large multi-national organisation, an SME or healthcare provider). It would be helpful if your assessment were to include, but not be restricted to, the financial impact of these proposals.

Rxchange has been conducting a poll to identify the average amount of ethical stock that pharmacies throw away every year because it goes out of date. The poll currently shows 4%. When this is factored against the £10.2B of the total prescriptions dispensed in the community in the UK, this suggests in excess of £400M is thrown away each year.

This means that on average every pharmacy in the UK could be throwing over £30K away per year – straight off their bottom line. A chain of 8 pharmacies could waste £0.25M. These figures do not include OTC waste nor the direct cost to the NHS for secondary care pharmacy waste.

Rxchange believe these regulations will affect corporate pharmacy to some extent, but assuming corporates are able to continue inter branch transfer of stock (IBT) the effect will be limited to the inability to procure hard-to-obtain items from anywhere but within their organization.

Rxchange believe independent pharmacies will be critically affected by these proposed changes.

There appears to be a disparity between what the proposed regulation will allow corporate multi-site pharmacies to do and what it will allow independent operators to do. i.e. pharmacy-to-pharmacy trade under section 10(7) will be restricted but there is no indication this will be applied to inter branch transfers within a corporate group. The proposals are therefore fundamentally anti-competitive and contrary to European trade law.

The proposals risk creating a monopoly market for manufacturers and their nominated wholesale channels and stifle independent competition. It does not reflect the "free market" described in (P54)

The proposals risk being perceived as an attack on community pharmacy and appears to do nothing to challenge the enormous trade of split-packs/re-packaged items which is part of several large corporate pharmacies operating practice.

We're left with the view that the stated objectives: "MHRA PUBLIC CONSULTATION ON MEASURES TO STRENGTHEN THE MEDICINES' SUPPLY CHAIN" remains highly debatable and that the proposals have more to do with serving manufacturer, wholesaler and corporate interests, rather than improving or strengthening the medicines supply chain.

- The proposals are anti-competitive
- The proposals tackle the problem from the wrong end of the supply chain
- The proposals do not consider the current UK economic climate
- The proposals are not appropriate for the perceived risk
- The proposals are not measurable
- The proposals are not enforceable

Criminal Sanctions

Criminal Sanctions

PROPOSALS

- Ensure that all potential offences associated with counterfeiting of medicines are adequately provided for in medicines legislation;
- Consider creating new criminal offences to deal with counterfeiting to address the possession and control by an individual or company of the counterfeit medicine with the mens rea of knowing that the medicines are counterfeit;
- Consider creating additional offences of possession of counterfeit medicines with the intention of supply, manufacturing counterfeit medicines and the possession of articles to facilitate the counterfeiting of medicines. We are also considering introducing an offence for failure to report a suspect counterfeit medicines to the MHRA;
- Develop clear guidance regarding aggravating and mitigating factors of the offences in terms of imposing the relevant sentence, such as, did the counterfeit medicine enter the regulated supply chain, reach pharmacies and patients, lead to a recall, cause adverse reactions in patients, etc;
- Imposing severe restriction on persons convicted, including precluding them from ever subsequently dealing in the trade of medicines.

Q. In the light of the increasing threat from counterfeit medicines in the supply chain do you think that there would be value in introducing a specific offence or offences in relation to counterfeit medicines?

Rxchange does not consider itself qualified to comment.

Q. Do you have suggestions as to other measures the MHRA could introduce within the current EU framework to further protect public health from the threat from counterfeit medicines?

Rxchange does not consider itself qualified to comment.

Q. Do you have any concerns that any of these measures could adversely impact on public health – please explain your concerns?

Rxchange does not consider itself qualified to comment.

Q. It would be very helpful if you could quantify any assessment of the impact of these proposals, as well as providing information about the type, and size of organization that will be affected (eg whether the impact relates to, say, a large multi-national organisation, an SME or healthcare provider). It would be helpful if your assessment were to include, but not be restricted to, the financial impact of these proposals.

Rxchange does not consider itself qualified to comment.

Proposals to amend Directive 2001/83/EC

Proposals to amend Directive 2001/83/EC

Rxchange cautiously endorse the proposals described in Annex B (Commission proposals to amend directive 2001/83/EC with regards to tackling the threat of counterfeiting).

We recognise that these proposals address counterfeiting from the top of the distribution chain, rely on good auditing, documentation and management processes. We also recognise it is likely that businesses will incur additional operating costs to comply with these standards. Rxchange does not consider itself qualified to comment on this further.

Rxchange endorse measures to enable identification, authenticity and traceability of medicines. This is in-line with Rxchange's stated policy on providing transparent and auditable transaction records as stock moves through the supply chain.

Conclusion

Conclusion

Having carefully considered the proposal document and consulted with our users, we are left with the view that the stated objectives: "Consultation on measures to strengthen the medicines' supply chain and reduce the risk from counterfeit medicines" remains highly debatable and that, generally, the proposals have more to do with serving manufacturer, wholesaler and corporate interests, rather than improving or strengthening the medicines supply chain.

- The proposals are not appropriate for the perceived risk
- The proposals are anti-competitive
- The proposals tackle the problem from the wrong end of the supply chain
- The proposals do not consider the current UK economic climate
- The proposals are not measurable
- The proposals are not enforceable
- The proposals will compromise patient healthcare

Observations on the consultation process

There are a series of opaque references to on-line stock exchange systems in the proposals. As Rxchange is the only sizeable UK service, we request that we are involved in face-to-face consultations at the next stage of this process (Timetable P3).

It is our opinion that issuing the document on the 18th December was inappropriately timed. Starting any public consultation less than a week before Christmas is bad practice, but especially unacceptable when Christmas is one of pharmacies busiest times of the year – not that the opinion of much of the pharmacy industry's opinion has been sought. This will have effectively wiped several weeks off the available consultation time and significantly reduced the awareness of this document. This can be quantified by the very limited amount of coverage this document has received in the pharmacy press.

The document published originally by MHRA failed to include 'Annex C - the MHRA's core consultation list'. This document was not made publicly available until 17th February 2009 - two months after the consultation started. This renders the consultation process fundamentally flawed.

The MHRA consultation document fails to demonstrate effectively the scale of the problem that it alludes to. No evidence is provided on the value or volumes involved (only the limited number of instances). Significantly, there is no stated threshold that the proposals intend to achieve. This should be publicly declared and is the core metric on the success of these proposals.

(P18) States "Increasing concern about the risks from counterfeit medicines can also seriously affect public confidence in the medicines available on the UK market". This is not substantiated or quantified in any way. We would like to see more qualified analysis of this statement as it underpins a significant *raison-d'être* of these proposals.

Although WDL holders have been directly advised of these proposals, neither independent pharmacy owners or Rxchange have been, despite the direct and significant impact the proposals may have on them.

The apparent references to Rxchange (P54) are flawed. They are inaccurate and misleading. The references to how the system 'facilitates' unregulated trade are potentially libellous. The MHRA consultation document contains numerous erroneous references to the nature of this trade and draws ill-informed and indefensible conclusions, implying that it is this trade which is bringing counterfeit products into the supply chain.

This prejudices a fair consultation and shows no understanding of the systems application or benefit. The system does not allow the trade of split packs and provides total transparency in its accurate description of the condition of all stock listed. Additionally, all transactions are fully auditable.

At no point have we provided access to the system to the MHRA or been consulted about the systems functionality. Accordingly any comment on the system's functionality/methodology would be based upon assumptions or unauthorised access to the site which is in itself unlawful, since access will have been 'stolen.'

Appendix A

How Rxchange works

Rxchange is a secure web environment for trading pharmacy stock between registered UK pharmacies and wholesalers. It connects companies with pharmacy stock to pharmacies wanting that stock. All users are manually validated as UK registered pharmacies or wholesalers before they are able to buy or sell on the site.

It allows UK pharmacies to sell stock that is no longer required and find hard to obtain items.

The system has been specifically designed for use in busy dispensaries and includes a range of features to simplify the buying and selling process, including order tracking, email alerts and invoicing.

Rxchange Ltd partners with the NPA to make the service available to UK pharmacies exclusively. The directors of the business are UK residents with extensive backgrounds in responsible commercial operating. The Clinical Director of Rxchange is a registered and practicing pharmacist.

Adding stock:

- Pharmacies add their own stock lines and details including description, strength and cost, most are acceptable but there are restrictions on controlled drugs, specials, unlicensed, and other prohibited products.

Buying stock:

- An email is sent to the vendor whenever a pharmacy makes an offer on stock – this and all other communication is archived.
- All sales have to be approved by the seller, through the systems pages of the site. Offers can be accepted or rejected and contact details are shown if the seller wants to discuss the offer
- A packing note, address label and invoice are automatically created
- Payment is normally made once goods are received – which affords the buyer further control over the buying process. A VAT invoice is normally sent with the goods, or these can be downloaded from the order detail pages

Core safety features of Rxchange:

- All users are manually validated to ensure only registered UK pharmacies and wholesalers checked against the published MHRA wholesaler list can use the system
- Secure https website
- System generates delivery notes, invoices and address label with the confirmed registered pharmacy address. Users cannot change their address and requests for change are always validated.

- Sellers must confirm that all stock loaded has not previously been issued to patients. The information is mandatory and the confirmation is stored and auditable
- Buyers must confirm that stock they are purchasing is for use in a retail pharmacy only and not being taken into a wholesale business - again this is mandatory and the confirmation auditable.
- Stock is automatically de-listed (removed from sale) before it reaches expiry date
- Short dated items are highlighted as part of the listing. System generated delivery notes and invoices also clearly show this information. This provides a more transparent system than purchasing from wholesalers who do not typically declare short date, or even expiry date, meaning pharmacies can only check viability of wholesale stock by checking each box.
- Buyer and seller information is only available to registered users, it is not possible for a non-user to "pass off" as a registered pharmacy
- Controlled drugs are automatically blacklisted from the system and the list is manually reviewed daily
- All transaction history is held online and can be retrieved 24/7. This is fully auditable unlike informal adhoc "swapping" of neighbouring pharmacy stock.

Benefits synopsis

- The most auditable and controlled approach to pharmacy stock exchange
- Stock provenance - sellers must verify that the product is "new stock" (not patient returned) and buyers must confirm it will only be for use in a registered retail pharmacy
- Hard to obtain items can be located – patient care is improved
- Pharmacy waste is reduced – good for business viability, economic competition and the environment

Rxchange allows UK pharmacies to sell stock that is no longer required and find hard to obtain items.

Appendix B

User feedback

We asked Rxchange users the following questions.

- Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?
- Q2. Do you believe this action will disadvantage your existing business?
- Q3. Do you believe this action may adversely affect you financially?

Further details can be found at:

www.rxchange.co.uk/news/MHRA-propose-changes-to-inter-pharmacy-trade.php#comments

There follows a representative sample of the responses. To respect confidentiality not all the responses we received have been published, but their views have been considered in this response document.

Superintendent Pharmacist - No (17 February 2009, 03:54:22 PM)

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?

No, all fakes have entered the supply chain by the mainline wholesalers and PIs.

Q2. Do you believe this action will disadvantage your existing business?

Yes it will be. This will increase waste and costs. Rxchange is also widely used for items that are temporarily unavailable and allow access to all pharmacies across the UK.

Q3. Do you believe this action may adversely affect you financially?

Yes, as we will be left with unsaleable and unuseable stock, that we cannot move. This will effectively increase costs to the NHS. The majority of drugs originate from when you have kept a particular product in stock for a patient for years and they die or move away. This stock ends up, as becoming redundant stock on our shelves, gathering dust and waiting to go out of date.

Dave G (17 February 2009, 03:55:26 PM)

Q1 No it won't make any difference to counterfeit stock as far as we're concerned.... we tend to buy/sell "unusual" expensive drugs which I can't see anyone bothering to counterfeit e.g. recently purchased Fosrenol 1000mg

Q2 Yes slightly

Q3 Yes slightly

Phil B (17 February 2009, 03:56:48 PM)

Q1. I do not believe that this measure will aid in insuring that counterfeit medication does not reach the individual. I believe this because the pharmacies who use RXchange are registered UK pharmacies who will have already obtained their (excess) stock through the correct and legitimate supply chain and so counterfeit medicines are unlikely to be involved with any inter-pharmacy transaction.

Q2. I believe RXchange to provide a useful service by which I can dispose of stock that is no longer required and is likely therefore to expire. The restriction of this service would disadvantage my business – but not to a significant degree.

Q3. I believe that the restriction of RXchange would adversely effect my business financially to a small degree.

I do not believe that the service offered differs from a multiple pharmacy chain that sends excess stock from one branch to another to prevent wastage and save costs. If you are to restrict RXchange, then you must consider preventing for example one Boots branch sending stock it no longer requires to another Boots branch, as in essence the effect is the same.

Hekta (18 February 2009, 10:51:34 AM)

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?

I think the idea to force all UK pharmacies wishing to trade pharmaceuticals with one another to obtain a WDL is unrealistic, overly burdensome and unnecessary and unlikely to reduce entry of counterfeit medicines into the supply chain. Pharmacies are already suitable places to store pharmaceuticals and supply them to patients. They are regulated by the Medicines Act and are inspected by the RPSGB to ensure compliance to the regulations. The public should have as much trust in obtaining noncounterfeit medicines from a pharmacy as a proprietor of another pharmacy would in obtaining the same product from that pharmacy. The level of trade between pharmacies is insignificant compared to the amount occurring between WDL holders and pharmacies. Effects of reducing counterfeit medicines by regulation at the pharmacy end would be proportionately ineffectual.

Far better to police and control entry of pharmaceuticals into the EU from known sources of counterfeiting countries. Greater expenditure on finding and fining counterfeiters would be a better use of resources than policing an already well regulated pharmacy sector. A pan European mechanism of encoding product data into barcodes to enable tracing and reconciliation would be more effective. This should be made part of Good Distribution Practice. In this way, the source and movement through the supply chain could be traced as in the food industry. Using fake holograms on packaging is unlikely to deter counterfeiters of expensive medicines.

Q2. Do you believe this action will disadvantage your existing business?

In the UK patients are not required to register with a pharmacy. Pharmacies are unable to plan accurately what and when to carry stock and how much. Patients conditions change, they move around and pass away. Consequently a pharmacy always carries a proportion of redundant stock. An average branch of ours writes off £20000 pa. If the NHS would compensate contractors with an extra £400million + costs of disposing of this waste then interpharmacy trade would reduce massively. In the mean time, pharmacies try to offset this loss by selling or exchanging stock between (licensed) branches. Further I would estimate that 5% of turnover would fall and gross profit would fall by 3% since trade between pharmacies is at a steep discount to trade prices. A reduction in suppliers would reduce competition and also drive up prices.

Q3. Do you believe this action may adversely affect you financially?

If contractors are not able to distribute medicines to other pharmacies and only to patients (unless in possession of a WDL), then either more stock will be thrown away which the government must compensate contractors for or the viability of community pharmacies providing a valuable service will be put under threat. In summary pharmacies must be given WDL exemption if trade constitutes less than 10% of their business.

keith s (17 February 2009, 04:03:31 PM)

This proposal is disproportionate will adversely affect my business and will result in financial loss

kmpharm (17 February 2009, 07:04:28 PM)

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?

Not at all; this is totally over-the-top. There is no proven threat and this will simply disadvantage community pharmacies in terms of their ability to manage their stock. The paperwork requirements will no doubt be onerous also.

Q2. Do you believe this action will disadvantage your existing business?

Yes

Q3. Do you believe this action may adversely affect you financially?

Yes

Nassir (17 February 2009, 07:06:57 PM)

I believe this is a money making exercise by the MHRA and all it does is add extra costs when we are going through recession. In addition if pharmacies can wholesale up to 5 % (under exemption from Wholesale deal licence) then why is there a need.

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain? NO as direct distribution has only become an anti competitive scheme. The European court is reviewing this issue. Small wholesalers go out of business and also have to obtain licenses when there is no need. That same product goes to the market so counterfeit issues would not arise. Pharmacy products if not sold to other pharmacies would be dispensed on prescriptions so where is the threat of counterfeit.

Q2. Do you believe this action will disadvantage your existing business? Yes because extra costs will be incurred. Q3. Do you believe this action may adversely affect you financially? yes as costs for inspections, annual fees, fees for variation etc will add up.

andrewmorpeth (17 February 2009, 07:09:15 PM)

As an independent pharmacist can i just say i find your service very useful and have used it on many occasions. I have never had any causes for concern with any dealings with other pharmacists also using your service. The issue of counterfeits that the manufacturers seem to be pushing hard i quite frankly have never seen any evidence of or have heard of any incidences with other colleagues.

Pfizer as well change their uk packaging through unichem and dont keep us pharmacists informed which i would have thought was an important counterfeit measure! I will agree to these new measures if there is ANY evidence this scheme is a source of counterfeit medicine entering the uk market. This scheme from the mhra would impact on the financial viability of my buisness!

It appears to be a bit overkill!

Pharmacist Bob (17 February 2009, 07:10:37 PM)

Q1. not proportionate and unlikely to have any impact on the supplies of counterfeit drugs. will however increase and potentially boost big-pharma's profits at the expense of small businesses. presumably, and rather conveniently, multiples will still be able to transfer between branches therefore giving them an advantage.

Q2. Little impact in my business as we do little of this activity. add all the little bits up though and nationwide it becomes significant.

Q3. will lead to more stock being written off at my expense.

Chris J (17 February 2009, 08:51:45 PM)

Firstly we actually hold a wholesale license as we supply a number of surgeries with pharmaceuticals and the total annual amount is such as to require such a license. If there was a risk of this license being withdrawn then it would seriously affect our business and would also affect those surgeries who rely on us for their day to day requirements.

I do not agree with this widespread concern about counterfeit products. Yes there are products with counterfeit drugs but not to the extent claimed by the manufacturers. It is more a case of manufacturers talking up this problem, in order to restrict export of their products to other countries, thereby undermining the large profits they make in such countries. Apparently it is the large volume of exporting being carried out by the large wholesale companies such as Unichem and AAH that has brought about much of this problem. The knock-on affect of this is that we now have shortages of many products in the UK retail pharmacy market which is denying patients their much needed medicines. It would be better if MHRA concentrated their efforts on introducing some form of regulation on this export trade with a view to looking after our own patients' needs.

Jayesh (17 February 2009, 08:52:33 PM)

I object to these silly proposals, I will lose money there will be more waste and the truth is that Big Pharam is try to protect the parallel trade Counterfeit is as excuse

John Foreman (17 February 2009, 11:37:04 PM)

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?

No. This will have a very negligible effect in our humble opinion!

Q2. Do you believe this action will disadvantage your existing business?

Yes. We rely on transfer of stock between Pharmacies to minimise wastage and expiry of stock.

Q3. Do you believe this action may adversely affect you financially?

Yes. Obtaining and maintaining a WDL is an expensive proposition

Rat Poison (18 February 2009, 10:46:02 AM)

My initial thoughts are this is yet another disproportionate and over regulatory action. The threat of counterfeit medicines entering the supply chain seems to me to be an imagined one, artificially created by large Pharmaceutical companies ,e.g. Pfizer trying to protect their sales of Viagra from unregulated internet sites <http://www.realdanger.co.uk/>. I would like to see the evidence of unlicensed medicines entering the legitimate supply chain and the number of cases where this has involved community pharmacies passing on counterfeit medicines to other pharmacies. I suspect the number of these in the last 5 years you could count on one hand.

If the MHRA would like to counteract the threat of counterfeit medicines they should clamp down on bogus pharmacy internet sites. The easy option of course is to target law abiding and regulated pharmacies.

How do they propose to stop transfers between different branches in the same pharmacy chain?

What quantity of a medicine would be regarded as sufficient to deal with a local emergency ?

How could this be regulated without increasing an already burdensome amount of bureaucracy that pharmacists working at the coal face already have to deal with?

The recent current direct supply arrangements, quotas, restricted choice of wholesalers imposed by manufacturers to stop 'Parallel Exporting' of their products mean that pharmacies have increasingly to turn to neighbouring pharmacies to maintain supplies to patients. I have had cause to contact my local MP recently over difficulty in obtaining supplies for patients prescriptions because of these new manufacturer imposed arrangements.

The proposed action would not overly effect my existing business, it may even benefit it. If I am forced to obtain a wholesale Dealers license, I would have to consider increasing my sales to other pharmacies and even 'Parallel Export' to justify the cost. With the low value of the £ at the moment the latter action could hopefully benefit my business and that of other community pharmacies substantially.

Of course the poor patient would suffer with increasing delays in obtaining medicines in the UK since they were all being exported.

That is, all except those patients buying Viagra online from dodgy internet pharmacies, who will be able to continue trading unfettered by any restrictions!!

Sorry if this has been a bit of a rant, but I believe Big Pharma and their current advertising campaign is the main reason behind this 'knee jerk reaction' by the MHRA. A more simple measure to end all the supply issue & counterfeit medicine problems at a stroke would be for the Government to:-

- a) ban all parallel imported and exported medicines and
- b) crack down on unregulated internet sites.

Meena B (18 February 2009, 12:05:14 PM)

I think us exchanging stock will not have any effect on counterfeit stock within the supply chain. And the measures now are not preventing this happening. The suppliers now have all the power to release stock to us and we are experiencing large out of stocks. I have to ring manufacturers direct and then I have to pay a handling charge to get these products via Unichem. I do not believe as a registered pharmacy we require a wholesalers licence nor should we pay for it! This would seriously undermine my profits and costs!

BP (18 February 2009, 03:25:59 PM)

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?

This will not reduce the threat of counterfeit stock

Q2. Do you believe this action will disadvantage your existing business?

My business and other small business will be disadvantaged. Borrowings from other and neighbouring pharmacies goes on all the time for the benefit of the patient .

Q3. Do you believe this action may adversely affect you financially?

This will reduce the profitability of my business as I will not be able to purchase in bulk to get the best discounts.

Graham Phillips (19 February 2009, 04:28:00 PM)

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?

No. It as bureaucratic, anti-competitive over-reaction. I'm quite sure it contravenes the government's own "Better Regulation" principles (available online) and could be challenged on that basis

Q2. Do you believe this action will disadvantage your existing business?
Absolutely. It will make RxChange non-viable for 99% of pharmacies

Q3. Do you believe this action may adversely affect you financially?
Yes. We will lose the benefits of RxChange savings at a time when the government claims it wants to support small businesses.

Have you asked NPA for lobbying support?

Eric G (23 February 2009, 09:56:20 AM)

I have never actually used Rxchange [but] The proposals by MHRA seem ludicrous and the idea that it will help to stop counterfeit medicines reaching the public is as ridiculous as this being given as the reason why so many of the manufacturers have altered their supply route to Pharmacies, when it is obviously a thinly veiled excuse to with hold more of the profit for themselves at OUR expense. In answer to your 3 questions:-

Q1. answer NO.

Q". answer YES.

Q3. answer YES most definitely, by more stock going out of date-but the manufacturers won't mind this at all coz they can then sell more!!!

Brian R (23 February 2009, 11:20:53 AM)

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?
No.

Q2. Do you believe this action will disadvantage your existing business?
Yes.

Q3. Do you believe this action may adversely affect you financially?
Yes.

Pharmacies are expected by the NHS to have medicines on the shelf ready to supply to patients. If doctor's surgeries suddenly decide to change their prescribing habits then medicines get left on the shelf which the NHS will not reimburse us for. This can cost pharmacies a lot of money. Bigger chains can overcome this by means of 'inter branch transfers' (IBT's) moving stock around. Moss Pharmacy used to run an email service listing stock that was needed/ difficult to get in other pharmacies. Independent pharmacies do not have this luxury. Newer medicines are getting more expensive and to expect pharmacies to bear this loss in money is unbelievable.

Regarding counterfeit stock, this problem only affects more expensive medicines. Some of the manufacturers of these products used holograms as an easy and quick way of identifying real product. These may not be cheap but as a % of the total price of the product then it won't be too much at least not for expensive items. If manufacturers are really concerned with dealing with the issue of counterfeit stock then they could have identified their stock in to smaller groups. Presently they are divided in to batch/lot number. There could be thousands of boxes within each batch. If they were to make batches of say 10,000 then have these subdivided in to lots of 100's with each lot going to a specified wholesaler, then there would be greater traceability of the item. All pharmacists could then check to see which

wholesaler their item originated from. This tied in with the hologram would increase security/safety.

Atul Patel (23 February 2009, 03:12:32 PM)

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?

No there is no evidence that transfer of stock between pharmacies would reduce the threat of counterfeit stock entering the supply chain. The efforts must be to put actions in place that will prevent them entering pharmacies via the main chain of supply in the first instance.

Q2. Do you believe this action will disadvantage your existing business?

I believe this action would limit your ability to reduce waste write-off and recovery of capital from stock, adversely affecting your business performance and profitability. Most definitely yes.

Q3. Do you believe this action may adversely affect you financially?

Yes and therefore risk access to Pharmaceutical services that the community current have come to rely on. Any action the MHRA must have a "NIL detriment" effect on current services available. This proposal will put the viability of current small independent Pharmacies at risk.

M Solanki (25 February 2009, 03:56:13 PM)

Q1. Do you see this as a proportionate and effective measure to reduce the threat of counterfeit stock entering the supply chain?

The MHRA proposal is definitely a disproportionate measure to reduce the threat of counterfeit stock entering the supply chain. We are all individually responsible professionals who at the heart want the best for our patients. We have traditionally discarded items unsuitable for supply at our own loss. No pharmacist would entertain counterfeit products.

All pharmacies only buy from reputable wholesalers and so a pharmacy buying surplus stock from another pharmacy does not increase the risk to public any more than buying the medicine from the main wholesaler direct. It is just a way of helping each other out.

Rxchange must reconsider how and which "small wholesaler" are allowed to trade on the Rxchange to ensure that these wholesalers do not increase the risk to public of counterfeit products any more than the "mainline wholesalers". In order to maintain a secure supply system, Rxchange must continually monitor and reassess the "wholesalers" who trade on the RxChange in order to maintain the credibility of this system of stock swap.

Q2. Do you believe this action will disadvantage your existing business?

Yes. Definitely

Q3. Do you believe this action may adversely affect you financially?

Yes, I believe it will make a difference of about 5% p.a. which is significant amount for a small business.

Mike E (25 February 2009, 10:59:00 PM)

1) This measure is not proportionate and would not be effective in reducing the threat of counterfeit stock entering the supply chain. The occurrence of counterfeit stock in the UK supply has never been linked to inter pharmacy trade which only ever occurs in relatively limited amounts anyway to shift items ordered for patients that are no longer required. If the proposals were implemented it would result in financial losses for pharmacies or just result in the practice occurring in a more secretive fashion which would increase the risks of counterfeits!! The MHRA would do better to focus their attention on internet sales which are a proven source of substantial quantities of counterfeits.

2) As highlighted above the proposed action would disadvantage my business by affecting my customer service - I would be less likely to order items for customers in advance of prescriptions for fear of being stuck with an expensive product I could do nothing with! NOT only would I suffer but more importantly, so would patients.

3) Yes - as above.

END