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

RPSGB response

Background

The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy. The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums. Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century, the Society is working towards the demerger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

The Society welcomes the opportunity to respond the Medicines and Healthcare products Regulatory Agency consultation on the measures to strengthen the medicines supply chain.

General comments

We believe, that in order for these proposals to be implemented efficiently and for there to be a real will to prevent counterfeits from entering the supply chain, then there should be an increased focus on bar-coding to enable authentication at the point of dispensing and the implementation of patient pack dispensing.

Wholesale dealers

The RPSGB supports the need to protect patients from counterfeit medicines entering the supply chain and understands that to do this will require changes to the way in which wholesalers are granted licences and regulated. It is important that any changes do not create a regulatory burden which may result in a shortage of medicines available for patients.

In particular, the proposal to require disclosure of applicant's criminal records and to require the applicant to demonstrate that they are a 'fit and proper' person is a positive one. Obviously, if the applicant is a registered healthcare professional this would imply that they are a 'fit and proper' person.

The requirement for payment in advance of fees for the licence may cause some difficulties in NHS Trusts due to their standing financial instructions.

We do have serious concerns around the removal of the £35,000 turnover concession regarding reduced fees. There are pharmacies in rural areas whose turnover is less than £35,000 but who provide a valuable wholesale service to other healthcare providers, such as hospices and out of hours providers. If they had to pay a licence fee this could prevent them from providing this valuable supply service.

NHS hospitals currently holding a Wholesaler's Dealer's Licence (WDL) may or may not claim this concession, depending on their NHS and commercial business. NHS hospitals currently supplying medicines across legal entities such as primary care trusts, hospices, prisons etc, do so under registration with the RPSGB as long as they do not exceed 5% of the sterling value of medicines they purchase. They mainly do this on a 'not for profit' basis and only seek to recoup the cost of that supply. For these hospitals, money will have to be identified to pay for and maintain a WDL and the associated inspection fees. Removing the reduced fees concession does not go hand in hand with a 'not for profit' service.

Responsible Persons (RPs)

The RPSGB believes that it would be appropriate for the Responsible Person (RP) to be a registered healthcare professional. This would ensure that the associated procedures, such as disciplinary procedures, revalidation and continuing professional development, were in place to support the person carrying out the role of the RP and to ensure public and patient safety. Ideally the RP should be a pharmacist - pharmacists oversee the dispensing of medicines to patients so it follows that a fellow pharmacist should oversee their distribution and handling. Pharmacists who may have to obtain a WDL will also need to have a RP. We are of the opinion that this role could easily be undertaken by the pharmacist, without the requirement to undertake the additional training course. We would propose a minimal exemption on this qualification training for registered pharmacists.

It is proposed that the MHRA holds the list of RPs but there is no clarity on how this list is maintained, how the competency of the individual will be reassessed and how an 'unfit' RP could be removed from the list. There is also clarity required on the cost of setting up and maintaining such a register and if registrants will be required to pay a fee to be on the register and / or a fee to have a certificate.

We support the proposal that a RP is not required to be constantly present at a site during hours of business but that they remain accountable and responsible for the wholesaling activity at that site. However, the MHRA needs to redefine what it classifies as a Deputy RP as and how this relates to / interacts with the term Wholesaler Qualified Person (WQP) – guidance on this would be appreciated.

We agree that a 'due diligence' obligation should be introduced into legislation including a requirement to notify suspicious events. However, much of the information that is listed as constituting due diligence is already held by a number of other parts of the NHS as it is a large component of central purchasing. The work load to pull all of this information together could potentially be expensive and time consuming. How due diligence applies to the NHS must be investigated, considered by MHRA and be possible to achieve.

We would like to offer our assistance in developing the code of practice for RPs, guidance around due diligence and the enhanced record keeping requirements and welcome the fact that these will form part of a future consultation. We would like to see the following areas covered in this Code of Practice:

- Storage and handling of medicines
- Appointment and screening of staff
- Development and maintenance of procedures
- Management of trading arrangements and supplier base
- Reporting of incidents and suspected defective or counterfeit products to appropriate authorities
- Assessment of returned stock for reuse or disposal
- Audit (internal and external)

We would recommend that these should form the basis of templates, provided by the MHRA, to ensure that standards are maintained and all wholesalers have the same standards of documentation

Medicines imported into the UK for export only

The RPSGB recognises the potential risks of allowing the import for export market to continue largely unregulated. However, it is also important not to over-burden legitimate operators who may be involved in the distribution of life-saving medicines. Some WDL holders supply in transit to third countries outside the EU with quota restrictions, some pharmaceutical companies do not allow such companies to have accounts so the MHRA will potentially have to evaluate categories of WDL holders and not band them into general categories.

The widening of the MHRA's powers to inspect premises of operators that conduct 'import for export' businesses is a positive move that should improve regulation of this area.

Storage and transit of medicines

Many hospital pharmacies manufacture products which they then trade with other organisations. Typically these are low volume specialist unlicensed medicines manufactured under a licence. The requirement to ensure probity of logistics distributors could be administratively burdensome if this is not clearly defined and reasonable.

If the MHRA requires all trans-shipment / logistic providers / freight forwarders to be listed on the WDL then there should be no charge for variations for the license holders when they change their storage and logistic providers. Variations can cost up to £500 a time so this is unlikely to be affordable.

We believe that another area that could benefit from a separate consultation is the area of medicines for export. The current definition of WDL holders for export needs more guidance and the MHRA would need to clarify this to manufacturers, pharmaceutical industry and suppliers of this special category and work would be required on the quotas, accounts and so forth.

Pharmacies

We would be extremely concerned if there was a complete ban on exemptions for pharmacies to holding a WDL and would strongly recommend that the 5% trading allowed under the section 10(7) is continued to be allowed. The costs to upgrade store facilities, additional monitoring equipment, additional staffing and / or staff training, as well as inspections costs and maintenance of facilities and equipment would not be affordable for many organisations. We would suggest that the requirement to hold a WDL would be disproportionate in relation to those who trade under 5% of their business.

Whilst we would support the trading of medicines on a not for profit basis, greater clarity is needed around what is meant by “occasional” and “small quantities” before we can support this. As the membership organisation for the pharmacy profession, the RPSGB must be engaged in the development of guidance which will clarify what is meant by “occasional”, “small quantities” and “not for profit”.

We are concerned that the suggested changes could lead to variations between those pharmacies who form part of a chain and those who are independent. All pharmacies should be subject to the same rules and standards and there should be no exemptions for any particular pharmacies that would be conducive to business. We are concerned that this could lead to conflicts of interest and issues with probity.

We would not support the proposal to limit the wholesaling under the Section 10 exemption to just inter-pharmacy trading. Pharmacies often supply small amounts of medicines to GP practices, care homes, hospices and out of hours providers upon receipt of a signed order from a doctor. If this was not allowed in the future, or only allowed if the pharmacy has paid and fulfilled all requirements to have a WDL, then these other healthcare services could suffer as a result. The implications of limiting trade to between pharmacies could lead to more complex logistics and more expensive methods of supply to those organisations who currently obtain their limited supplies form pharmacies.

The limitation of the exemption in the way suggested could affect the pharmacist's relationship with GPs and other healthcare professionals who currently rely on them to supply medicines under the Section 10(7) exemption. When we are talking about supply of medicines between pharmacies or from pharmacies to other healthcare providers we are invariably talking about medicines which have already entered the supply chain. Any proposals which will alter the way these systems work now will, we believe, increase bureaucracy and act as a disincentive for smaller pharmacies which could lead to increased delays in patient treatment.

If there are potential problems from pharmacies trading in medicines from unauthorised sources, one solution would be to exempt pharmacies where they have originally obtained the drugs from existing UK licensed wholesalers. If the correct checks and balances are in place when the wholesaler obtains the medicines, there is little point in placing the same checks and balances on the individual pharmacy wishing to pass them onto another pharmacy or registered healthcare professional. It would seem unnecessary to repeat the process when the medicines are already part of the UK market and pharmacists would not be expected to perform any further checks if the medicines were to be dispensed to a patient against a prescription.

Clarity is also required around the situation where a pharmaceutical rep provides a doctor, or other person, with 'starter packs' of medicines as this could also be considered as wholesaling.

The limiting of the exemption could also have a negative impact on the movement of services from secondary to primary care, which is currently the direction of travel endorsed by the government.

The proposal to develop standards for the disposal of unused and discarded packaging in pharmacies is not mentioned in this consultation but was mentioned in the previous consultation. Such standards need to be clearly defined and should not require the pharmacist or pharmacy staff to be involved in lengthy disposal techniques. Also, waste from other sources such as GP practices, care homes, hospital wards would also need to be considered.

Criminal sanctions

Counterfeit medicines do pose a huge risk to patient safety if they enter the supply chain. It is therefore right that these risks are recognised and appropriate penalties imposed.

Where offences are created for those handling and supplying counterfeit medicines there should be consideration given for statutory defences if the individual could not have reasonably known that the medicines were counterfeit. For example, if a pharmacist obtains medicines by way of wholesale from an entirely appropriate route and a counterfeit medicine was found to have entered the supply chain it would not be proportionate to prosecute the pharmacist who was mislead and who could not have reasonably known that the medicine was a counterfeit.

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