GHP Guild of Healthcare Pharmacists

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DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION

CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

Response from the Guild of Healthcare Pharmacists.

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite.

Following the receipt of information on the consultation paper from the Procurement and Distribution Interest Group of the Guild, we have considered the paper and wish to offer the following comments:

UK Hospital Sector

The UK hospital sector may only have seen one or two cases, if any, of counterfeit medicines thus far. Hospitals in the UK purchase most of their medicines under contract from established suppliers following a QA review. Approximately 40% of medicines are purchased from wholesalers, the rest direct from the manufacturer/ contractor. In essence, Hospitals have not experienced significant problems with counterfeiting to date, although this might become a problem if not managed appropriately.

Other Methods to Control Counterfeiting

The use of such a technical solution as proposed by the EU should not be seen in isolation.

Although some cases of counterfeit medicines have occurred in the UK (only a few each year), the general view is that the issue is of less significance here, than perhaps other countries in the world. In the UK, we perhaps have greater control over the wholesaling process and wholesalers as well as having professional standards under regulation for the distribution/dispensing process via community pharmacists. Purchasing over the internet however is still open to wide exploitation.

The MHRA licensing system does make entry of counterfeit medicines into the UK perhaps more

difficult than many other countries in the world. Despite this the existing wholesaling process is currently under review by the MHRA because of this risk and will inevitably have more controls. The new guidance will most probably be launched later this year or the next so that counterfeit medicines will be even harder to introduce.

The MHRA's approach appears to be focussing on trying to tackle the counterfeit problem by looking at the people who move medicines in the supply chain and preventing them from obtaining medicines from illegitimate sources. This methodology seems to be working and does not rely on the technology described.

Any use of technology as proposed by the EU should therefore be considered in association with the other control mechanisms such as licensing, inspection, etc. Forcing individual countries down a possible expensive technological route without recourse to other simpler control systems such as managing Internet sales, may not be considered a prudent policy.

Community pharmacies can buy from any supplier so the same security is not available to patients as in the hospital sector.

Benefits of Unique Identifiers

The use of unique identifiers will, of course, assist the process by developing a method of identifying where a counterfeit problem has occurred. The use of such a complex monitoring system to stop counterfeiting seems like a 'sledge hammer to crack a nut', especially if the country does have other sophisticated mechanisms to control the supply chain as in the UK (see above).

There are, however, other benefits from having unique identifiers. The key benefit to the NHS might be the reduction of medication errors - a system to be managed more at the point of dispensing or by the bed side during medicine administration, as expired stock could be more readily identified. The greatest benefit of such a system would be the introduction of a method of tracking batch numbers so that product recalls within hospitals could be undertaken more effectively. There may also be further efficiency benefits through the greater use of robotic technology as all products will have to have some sort of code as the range is incomplete at present. The software for scanning unique identifiers needs optimally to interface with other hospital pharmacy systems, and not be 'stand alone', if it is not to create an extra layer of data which is lost to information systems.

Benefits in secondary care in the UK may be difficult to realise due to the variety of ways medicines are managed and distributed through a variety of channels e.g. prepacks in A&E, ward stocks, patient own drugs, centralised stores. This will require a standardised process for authentication perhaps on receipt from the wholesaler. The model suggested has been primarily considered for primary care utilisation where the risk is currently greatest and is therefore most appropriate.

Management of Process

The key element of change proposed will be the addition of the expiry date and batch number (both of which are already available on products) to the product code/unique identifier. The way this is achieved may vary between suppliers and therefore an EU methodology would assist with standardisation thus reducing complexity and cost.

Some countries in the EU already use serialisation such as Belgium, Italy and Greece. We understand that the centralised database for these countries contains 734 million records about different packs and has been successful in detecting 7 instances of possible falsified medicines. We also know that the whole supply chain information on individual products is not traceable by the manufacturer so there is no counter-competitive advantage of having the identifiers.

Choice of Technology

The only realistic and affordable solution is the 2D bar code solution. The RFID method will be more expensive and will be harder to implement from the technological perspective. The linear bar code will not be able to hold sufficient information on a label for small packs. All our existing technology, where it is available, is able to read linear bar codes. Our robotic companies are currently working on a facility to read 2D. No one is working on RFID.

Location

Work will need to be carried out in the hospital stores or dispensary in addition to the wholesaler otherwise this would defeat the object of monitoring the whole supply chain.

The location where the check should be made in the hospital will be variable according to circumstances. Those stock items that do not go through the dispensary will need to be checked in the stores/distribution area e.g. ward stock, emergency boxes. Stock items issued to the dispensary will need to be checked on receipt.

The UK also uses a number of Unlicensed Medicines and repacks. Methods will need to be developed that will enable these providers to add bar codes on to their products. This might be cumbersome for small batches and increase costs and cause delays.

Costs

(a) There will be a number of additional costs with the introduction of the 2D bar code. Manufacturers are picking up costs.
(b) There are some costs associated with the hardware (e.g. readers) which is in fact most probably the smaller proportion of the cost.
(c) The largest cost will most probably be the rewriting of pharmacy computer systems to utilise the information on the bar code itself, and creating an interface with the scanning software.
(d) Payment to Authenticating Company – there will be an inevitable additional cost to pay a company who will need to maintain the product data base and the on-line access which provides no delay in reading the product. There will be an increase in cost of the medicine due to the labelling retooling and change to production line system manufacturer.
(e) There will be additional time required to undertake the authentication. This time will depend upon the responsiveness of the data management system and the local access to the internet. Access to the Internet will be paramount. A typical large teaching hospital may be required to authenticate over 4 million packs per annum.
(f) Additional time will be required to ‘manage’ false results, errors and other system problems.

We hope that our comments are of assistance. Our reply may be made freely available.

Yours faithfully

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