Submission of comments on the detailed rules for a unique identifier for medicinal products for human use and its verification.

CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION
(Falsified Medicines Directive 2011/62/EU)

Comments from: Tim Root, Specialist Pharmacist, Clinical Governance & Technical Services, East & SE England Specialist Pharmacy Services.

Consultation item n°1: Please comment on points 1 and 2 (policy options n°1/1 and n°1/2).

The choice of technical specification for the unique identifier should NOT be left to each manufacturer to decide. If manufacturers are allowed to dictate what system is used this will mean everyone else in the supply chain will be forced to purchase a variety of scanning systems. This would be particularly problematic in pharmacies (hospital or community) who receive deliveries of medicines from wholesalers. The Commission should set out in the delegated act details concerning the serialisation number (see point 2.1) and the carrier (see point 2.2).

Consultation item n°2: Where do you see the advantages and disadvantages of the approach set out in point 2.1.1?

A unique identification number on each pack will be of benefit to manufacturers and regulatory authorities in aiding traceability. It will also allow minor defects (e.g. lack of a patient information leaflet or lack of expiry date printed on a particular box) to be pinpointed to a specific point during a packaging and labelling operation. The disadvantage will be in the costs associated with upgrading label printers and software and in acquiring the appropriate scanning technology in in pharmacies.

Consultation item n°3: Where do you see the advantages and disadvantages of the approach set out in points (a) and (b) of point 2.1.2?

The caopacity to include additional information such as the batch number and expiry date into the unique identifier will have a positive benefit for stock control, reducing the risk of dispensing expired stock and facilitating retrieval of any medicine subject to a recall by the manufacturer or the regulator.

Consultation item n°4: Which of the two options set out under point (c) of point 2.1.2 is in your view preferable?

Member States should not be allowed to add requirements to 2011/62/EU labelling rules. I have no comment on national reimbursement numbers.

Consultation item n°5: Please comment on the three concepts described under point 2.2. Where do you see the benefits and disadvantages of each of the three concepts?

Linear barcodes represent the cheapest option and many pharmacies already have the linear bar code readers. Linear barcodes do not, however, allow useful extra information such as batch numbers and expiry dates to be easily incorporated. 2D barcodes therfore probably represents the best compromise between cost and the level of information that can be encoded. Whichever system is chosen it should be implemented universally – see my comment with on Consultation item 1.

Consultation item n°6: Regarding point 1 (policy option n°2/1), are there other points of dispensation to be considered?

As a general principle, the most useful information will be obtained by scanning and verifying packs at the point of dispensing in the pharmacy. This will also provide the highest level of assurance that the medicine handed to the patient is genuine and will generate more accurate information about medicines usage. It will also have advantages in reducing dispensing errors. However, many medicines are administered in the hospital environment from stock held in clinical areas such as wards, theatres, accident and emergency departments and intensive care units. In these areas it may not be practical or in the patient's interest (when speed of treatment is paramount) to scan medicines for authenticity. It is not possible to always identify in advance which packs of medicines received are destined for dispensing direct to patients and which are destined for clinical areas. It would be unreasonably burdensome to scan stock twice (on receipt and at the point of dispensing) and may not be possible if the database holding the information on the unique identifier only allows an organisation such as a hospital to verify the medicine once (a second scan of the same pack therefore appearing falsely as a counterfeit).

Consultation item n°7: Please comment on the three policy options set out in points 1 to 3.

Point 1: please see my response to Consultation item 6 above. Points 2 and 3: Falsified medicines will best be kept from the legitimate supply chain if everyone in the supply chain is responsible for the systematic verification of medicines that pass through their control. Therefore I support option 3.

Consultation item n°8: Please comment on the three policy options set out in points 1 to 3.

A pan-European repository is the best solution and links to my belief that a single identification system dictated by the EU is the best approach (see reply to Consultation item 1). This will benefit manufacturers, who will have only one system into which to load information they will not be individually responsible for its maintenance. The disadvantage of this approach is that if the database crashes the supply of medicines across the whole of the community could be frozen? There are also security concerns.

Consultation item n°9: Please comment on point 4.1.

Database security will be of paramount importance and as noted in the concept paper.

Consultation item n°10: Please comment on points 4.2 and 4.3.

Security of personal data will be of paramount importance. Point 4.3: It is vital that repackaging of medicines is allowed under appropriate controls, for both commercial operators and for the NHS. It is important to consider whether an overlabelling operation, where original packs are labeled with directions in advance of use (e.g. the supply of oral contraceptives through family planning clinics, packs of antibiotics or analgesics supplied from Accident and Emergency departments when the pharmacy is closed) would be required to comply with this directive. Some medicines supplied by manufacturers only in bulk containers (e.g. packs of 100 tablets) are broken down into smaller units within a hospital pharmacy for subsequent supply. We strongly believe it would be a regulatory burden to expect these NHS repacking operations to have to comply with this directive. Such bulk medicine packs would be scanned on receipt into the hospital and not again at issue to the patient (see the response to Consultation item 6).

Consultation item n°11: Which approach seems the most plausible from your view?

Identification criteria for any black or white list should be based on the name or names of the active pharmaceutical ingredients. However, see my comment below on Consultation item 12.

Consultation item n°12: Please comment on the quantified approach set out above. Operation of a black list and a white list is likely to be unreasonably burdensome and potentially unsafe. As previously noted, there are positive benefits to be gained from unique identifiers on all packs. Mixed deliveries of medicines from many different manufacturers would pose a continual major challenge to recipients. The database might assume an inappropriately scanned item with an unknown unique identifier was a counterfeit. Operation of two lists might encourage counterfeiters to target white list medicines. All medicines must be subject to the same level of control or the whole exercise could rapidly become a costly failure.

Consultation item n°13: Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

An unwanted effect of this legislation could well be an increase in medicines wastage with consequent environmental and cost implications. If repackaging is not allowed except when unique identifiers and tamper proofing is reapplied after repackaging, repacking of medicines within some NHS hospital pharmacies will be discouraged. This will result in whole packs being issued (e.g. 28 tablets) when only one or a few doses is required e.g.prior to a medical or surgical procedure. The patient would then be directed to throw the rest of the pack away It may also encourage the issue of excess medicines which pose a threat to patient safety or a risk of diversion & abuse. Unused ward stock medicines are returned to the hospital pharmacy for examination and potential re-issue. This may not be possible if the medicine has been scanned and verified at the point of first issue.

Inclusion of excipients in the scope of the Directive is commended but this may have a disproportionate impact on essential small manufacturers. GMP Compliance for management of excipients stocks should be included in the scope of inspection of manufacturers' premises by regulatory authorities.

Tim Root, April 26th 2012.