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: The NHS Pharmaceutical Quality Assurance Committee

The NHS Pharmaceutical Quality Assurance Committee is comprised of the lead specialist Quality Assurance Pharmacists who work for the National Health Service (NHS) in the United Kingdom. Many NHS Hospital Pharmacy Departments hold either a manufacturing licence, a wholesale dealer's licence or both and therefore will be affected by the requirements of EU Falsified Medicines Directive. We are therefore commenting on these proposed changes with respect to the impact they may have on NHS hospital pharmacy practice in the United Kingdom.

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

We are of the strong opinion that the choice of technical specification for the unique identifier should NOT be left to each manufacturer to decide. As noted this would be of benefit to some manufacturers who already have systems in place, though there is no indication in the concept paper what proportion of manufacturers this might be. However, it is certain that if manufacturers are allowed to dictate what identification system is used this will mean everyone else in the supply chain will be forced to purchase a variety of scanning systems to verify the authenticity of medicines. This would be particularly problematic in pharmacies (hospital or community) who receive deliveries of medicines from wholesalers as a mixed order of medicines from many different manufacturers. Therefore we recommend that 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?

We believe that a unique identification number on each pack will be of benefit to manufacturers and regulatory authorities in aiding traceability. It will also be advantageous in allowing incidents of 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 time point during a packaging and labelling operation. This will improve the Quality Management System by allowing minor defects and customer complaints such as these to be investigated more accurately for root cause and to help establish corrective and preventative actions. The disadvantage will be in the costs associated with upgrading label printers and software in NHS hospital pharmacy departments that manufacture medicines and in pharmacies in general in acquiring the appropriate scanning technology.

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?

We believe that the ability to include additional information such as the batch number and expiry date into the unique identifier will have a positive benefit for stock control in terms of better stock management, reducing the dispensing of expired stock and in speeding up the 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?

We commend the principle that Member States are not allowed to add requirements to 2011/62/EU labelling rules, however we 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 most pharmacies already have the linear bar code readers or could purchase them. The use of linear barcodes does not allow useful extra information such as batch numbers and expiry dates to be easily incorporated. We believe that the use of a 2D barcode probably represents the best compromise between cost and the level of information that can be encoded by the unique identifier. We note that very few NHS hospital pharmacies in the UK are currently equipped with suitable scanners to read such 2D barcodes. This would cause additional problems for those hospital pharmacies that already have dispensary robots currently in operation, as these would need to be equipped and reprogrammed to accept this new technology. However, which ever system is chosen it should be implemented universally – see our comment with respect to 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 point of principle we believe that 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 generate more accurate information about medicines usage in the NHS. 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. Therefore medicines supplied in this manner would need to be scanned on receipt into the pharmacy before delivery to clinical areas. It is not possible to always identify in advance which packs of medicines received are destined for dispensing from the pharmacy direct to patients and which are destined for clinical areas. It could be burdensome or time consuming 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). Therefore it may only be possible to scan medicines once on receipt into the hospital pharmacy.

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

With regard to point 1 see our response to Consultation item 6 above. With regard to points 2 and 3 we strongly believe that 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 we support policy option 3.

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

With regard to the database repository of unique identifiers the supply chain of medicines within the EU is highly interlinked between different member states therefore, to protect the EU supply a pan-European repository is probably the best solution. This also ties in with our belief that a single identification system dictated by the EU is the best approach (see our reply to Consultation item 1). This will benefit manufacturers in that they will have only one system to load information on to and will not have to be responsible for the maintenance of such a system (though they

might be asked to make a contribution towards its upkeep?). The disadvantage of this approach will be that if the database crashes this will possibly freeze the supply of medicines across the whole of the community. There would also have to be strict security on any such database to prevent it from being "hacked" into.

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

We have no further comment on commercially sensitive information other than those points already raised. 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.

As with Consultation item 9 above, the security of personal data will be of paramount importance. With respect to point 4.3 we strongly believe that it is vital that repackaging of medicines is allowed, provided that appropriate controls are in place, both for commercial companies and for the NHS in the UK. 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. Also, some medicines are supplied in bulk containers (e.g. packs of 100 tablets) and 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 repacking operations within the NHS to have to comply with this directive. This may not be necessary if the bulk medicine packs (that are repackaged into smaller quantities) are scanned on receipt into the hospital and not again at issue to the patient (see our response to Consultation item 6).

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

We believe that the identification criteria for any black or white list should be based on the name or names of the active pharmaceutical ingredients. However, see our comment below on Consultation item 12.

Consultation item n°12: Please comment on the quantified approach set out above.

We believe that the operation of a black list and a white list may not be practical or safe. As noted in our comment to Consultation item 3 there are positive benefits to be gained from having unique identifiers on all packs. Pharmacy staff would be unsure which items in a delivery of medicines from a wholesaler containing a mixed order of medicines from many different manufacturers would require scanning and which would not. This could cause problems if a white list item was scanned if the database then assumed the unknown unique identifier being presented was a counterfeit. The operation of two lists would only encourage counterfeiters to target white list medicines as they would see these as a soft target, not being subject to the same level of scrutiny as those on the black list that would have to carry a unique identifier. Although a risk based approach would seem sensible if say only 0.5% of medicines are subject to counterfeiting and 99.5% are not. However, we believe that all medicines must be subject to the same level of control otherwise this 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.

We are concerned that an unwanted effect of this legislation will 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, this may discourage the repacking of medicines within NHS hospital pharmacies. This could result in whole packs being issued (e.g. 28 tablets) when only a single dose of a medicine is required prior to a medical or surgical procedure. The patient would then be directed to throw the rest of the pack away. Within the hospital setting medicines may be issued as stock to wards or for patient use in the hospital and then not be used or only part used. Currently such unused medicines that have not left the hospital are returned to the hospital pharmacy for examination and reuse. This may not be possible if the medicine has been scanned and verified at the first dispensing as it could not then be scanned again without triggering an alert that the appearance of a duplicate unique identifier was a counterfeit.

The inclusion of excipients into the Falsified Medicines Directive is commended, however, we are concerned that this will have a disproportional impact upon small manufacturers such as NHS hospital pharmacies that hold manufacturing (specials) licences. We would urge that the inspection of manufacturers of excipients for compliance with the current standards of good manufacturing practice be a responsibility of the regulatory authorities rather than the manufacturing licence holder.