

**DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION RESPONSE TO THE CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION**

*Since March 2010, the NHS together with leading manufacturers, solution providers and policy makers have collaborated as part of a GSI facilitated working group; the 'Supply Chain Working Group'. This Group has worked closely with stakeholders to support the development of harmonised standards and solutions to address market requirements in the UK and internationally. This consultation response is an output of this work and represents the consolidated views of this Group.*

**A. CONSULTATION TOPIC N°1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER**

**1. Policy option n°1/1: Leaving the choice of the technical specification to the individual manufacturer**

**2. Policy option n°1/2: Harmonisation through regulation**

**Consultation item n°1: Please comment on points 1 and 2 (policy options n°1/1 and n°1/2). Where do you see the benefits and disadvantages of each policy option?**

*The Group have a strong preference for Policy Option 2; which calls for harmonisation of the technical specification across Europe and for this being ensured through regulation. This will deliver a standardisation of process to the pharmacy which will assist in making comparisons and when entering data. This is especially relevant where drugs are purchased from across Europe.*

*It is the view of the Group that use of 2D data matrix implemented to GSI standards would achieve the desired harmonisation..*

*The code should include the product's GTIN, expiry date, batch number and unique serialisation number.*

*Due to there being a pan-European supply chain which sees regular movement of medicines across national borders, any effective coding and identification system must be able to exchange information with other countries and the systems in place in that country, thus it is the view of the Group that a harmonised standard coding system be implemented across the EU.*

*We do not envisage any disadvantages of this process.*

**2.1. Regulation of the composition of the serialisation number**

**2.1.1. Manufacturer product code and pack number**

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

*The identification of the manufacturers' serialisation number for pack is preferred. We do not believe that all the pack information need to be included in the pack code. The Global Trader Item Number can be used as the key to open the repository to retrieve all the necessary data elements held for products, including manufacturer pack number. Enabling the identification of individual packs at the point of dispensing has huge advantages to patient safety and anti-counterfeiting.*

*For the bar code technology to be implemented fully it is essential that a data base containing all GSI Global Trader Item Numbers (GTIN) for all medicines used in the UK is updated and maintained and freely available to the NHS. This is likely to be the NHS preferred medicines terminology, the NHS dictionary of medicines and devices (dm+d) database see [www.dmd.nhs.uk](http://www.dmd.nhs.uk)*

*We do not envisage any disadvantages with this approach.*

**2.1.2. Additional product information**

**(a) Batch number**

**(b) Expiry date**

**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? Please comment.**

*The Group have a strong preference for both data elements to be included in the pack code. We believe that both are essential and should not be separated. The automatic machine reading of such data elements to populate a patient electronic health record would be of huge benefit to patient safety through the use of this functionality.*

*Using 2d bar codes for individual serial numbers enabling batch number and expiry date information to be available electronically at the point of dispensing. This will provide a method to better track batch numbers supplied to individual patients and will facilitate patient level batch recall and provide an electronic alert if dispensing of expired or short date stock is attempted. Furthermore, electronic prescribing could be further facilitated with the use of machine readable data for medicines.*

*Routine use of bar code technology in the dispensing process would release pharmacists from the dispensary where they spend a lot of time checking dispensing accuracy, to the front of the dispensary to spend more time with patients and carers and to progress medicine optimisation activities.*

*We do not envisage any disadvantages through this approach.*

### **(c) National reimbursement number**

**Option 1:** the national reimbursement number is replaced by the abovementioned serialisation number.

**Option 2:** The abovementioned serialisation number includes the national reimbursement number. In this case, the serialisation number could be composed as follows:

- **Manufacturer Product Manufacturer Product code (which includes the prefix of the country)**
- **Unique identification number of the pack**
- **National reimbursement number**
- **Expiry date**
- **Batch number**

**Consultation item n°4: Which of the two options set out under point (c) of point 2.1.2 is in your view preferable? Where do you see advantages and disadvantages? Please comment.**

*The UK does not use the re-imburement number; therefore we have a preference for Option 1. However, we do believe that there needs to be a clear differentiation between the code which includes re-imburement numbers and the code that does not, if re-imburement information is included in the code.*

## **2.2. Regulation of the technical characteristics of the carrier**

### **2.2.1. Linear barcode**

*Linear barcodes are not expensive, but the length of barcode needed to carry all the additional data elements; such as batch number, expiry date and serialisation codes would make the code too long for linear codes to be a viable option to track medicines. Space considerations prohibits the use of linear bar codes on some small packaging, a good chunk of dispensing errors come from vials that do not contain a code of any sort which argues against use of larger bar codes.*

*The advantage of using this code is that the code reading devices in current use in UK pharmacy are currently able to read linear barcodes and no upgrade in technology would be required.*

### **2.2.2. 2D-Barcode**

*We are in unanimous agreement that product verification using machine readable codes be used as a means of reducing errors within pharmacy.*

*We propose that the scanned code be verified at the point of dispensing against a database of verified manufactured products. This means that pharmacists can rapidly confirm the status*

*of each pack before dispensing it to the patient. The implication is that the code be used to identify the pack, the product, the expiry date, batch number and where necessary unique serial number. The amount of information needed to be contained in the code means 2D would need to be used and not linear barcodes.*

*There is a significant amount of wastage in hospital robotic pharmacy through an inability to track the batch number and expiry, thus use of 2D coding will offer a massive cost saving to the NHS.*

*2D carriers are more expensive than linear codes, but are sufficient to carry all the necessary data elements in a code which could be applied to a medicine label without compromise.*

*The cost of producing a serialised code dynamically within the production line could be problematic to manufacturers, though not insurmountable. Any costs borne initially by the manufacturer may be passed on to the customers, increasing drug costs within the healthcare industry.*

*The downside of the use of 2D data matrix codes is that the scanning devices currently deployed in the UK healthcare industry are not all sufficiently able to read 2D codes thus a degree of upgrading this technology will be required. Automated dispensing systems are widespread, particularly within secondary care and the scanners would need to be upgraded on these systems.*

### **2.2.3. Radio-frequency identification (RFID)**

*RFID is the most expensive option but we do not believe this is necessary for use on medicines as sufficient information can be contained in 2D barcodes at a lower cost. Furthermore, many medicines are "water-based" for example, injections, oral liquids, eye/ear/nose drops. "Water-based products" cannot make use of RFID as the technology does not work well in this environment making standardisation problematic.*

**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? What are the costs for each concept? Please quantify your reply, wherever possible, by listing for example:**

- costs for reading devices for the different carriers;**
- costs for adapting packaging lines of medicines packaged for the EU market.**

*It is the view of the Group that 2D carriers are the most cost-effective solution to be explored here.*

## **B. CONSULTATION TOPIC N° 2 - MODALITIES FOR VERIFYING THE SAFETY FEATURES**

**1. Policy option n°2/1: Systematic check-out of the serialisation number at the dispensing point**

**Consultation item n°6: Regarding point 1 (policy option n°2/1), are there other points of dispensation to be considered? How can these be addressed in this policy option?**

**2. Policy option n°2/2: As in policy option n°2/1, but with additional random verifications at the level of wholesale distributors**

**3. Policy option n°2/3: As in policy option n°2/1, but with additional systematic verification by the wholesale distributors**

**Consultation item n°7: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Quantify your response, wherever possible. This applies in particular to the:**

- number of wholesale distribution plants;
- costs for adapting such plants;
- duration of scanning of the serialisation number;
- number of pharmacies, including hospital pharmacies;
- number of medicinal products dispensed by pharmacies and a hospital pharmacy.

***Policy Option 1:***

*Dispensing is complex in the UK as the point of dispensing includes many different environments. The 'point of dispensing' in the UK includes hospitals, outpatient clinics, accident and emergency rooms, care homes, doctor surgeries. The point of dispensing can also include dispensing into dosette or other compliance aids and devices, which would add further complexity, therefore verification in hospitals is not possible at the point of dispensing due to the complexities of the supply process. A better approach to verification would be to scan product upon receipt into the hospital.*

*Some issues for consideration include:*

*Care homes may not have the technology to scan product at the point of dispensing.*

*Doctors may keep drugs remotely for use for mobile on-call and out of hour's appointments. This would be problematic for scanning.*

*Dosettes and compliance aids cause a particular issue with ascertaining the point of dispensing and what happens where one pack is used for several patients. Similar issue would arise with use of part packs which is particularly prevalent in the UK.*

*It is the opinion of the Group that it should be possible to cancel an action if an error has been made in the supply of the product, for example, if the patient didn't want the medicine*

*and the medicine had not left the premises. Returns back into stock for re-issue to another patient should be considered. How will this information be put back into the repository once it has been booked out at the point of dispensing?*

**Policy Option 2:** *may be a possibility as a compromise position.*

**Policy option 3:** *would cause a particular problem to wholesalers as wholesalers use automated picking systems such as A-frames with high throughput, they would not have sufficient time in their processes to verify every product line and pack as it is issued. To scan each pack they would have to implement manual processes which would add considerable time and cost to the picking and order processing timescales.*

*That the verification should take place as near to dispensing as possible e.g. at “goods in” at the pharmacy also include spot checks at wholesalers but not systematic at wholesalers.*

### **C. CONSULTATION TOPIC N°3 - PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM**

**1. Policy option n°3/1 – 'stakeholder governance'**

**2. Policy option n°3/2 – EU governance**

**3. Policy option n°3/3 – national governance**

**Consultation item n°8: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, wherever possible. This applies in particular to the estimated one-off costs and running costs for a repositories system. Where possible, please provide information on past experiences with a repositories system at individual company level and at national level (taking into account the experiences of Member States and companies).**

*The Group have a preference for European Governance of the repository. However an alternative position would be for national governance under the proviso that countries be allowed to work together and collaborate e.g. BeneLux etc. We do not see the value in duplicating this work country by country due to the cost of setting up and managing the repository system. There should be sufficient flexibility to implement national or regional solutions within the repository as required*

*In addition to using a common standard for pack identification across Europe, all governance systems and repositories should be configurable to enable the fast and easy exchange of product information as required in order to allow any pharmacist across Europe to check whether the pack has been dispensed before, irrespective of its country of origin.*

*Should a system of National repositories be implemented, each Country's repository should be required to meet equivalent minimum quality assurance requirements. Without this, there is the risk that counterfeiters would be able to exploit gaps between national systems to insert falsified medicines into the legitimate supply chain*

*In addition we recognise that there are two models under discussion, at this stage we support either option (EDQM or EFPIA models) and until the discussion is more mature we cannot decide between the two.*

#### **4. Other issues related to the repositories system**

##### **4.1. Information of a commercially sensitive nature:**

- **Information that allows the number of packs manufactured to be established;**
- **Information that allows the point of dispensation of a pack to be established;**
- **Information that allows the point of re-packaging of a pack to be established.**

**Consultation item n°9: Please comment on point 4.1. Are there other items of information which should be taken into consideration when addressing the issue of commercially sensitive information in the delegated act?**

##### **4.2. Protection of personal data**

##### **4.3. Re-packaging of medicinal products**

**Consultation item n°10: Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?**

*4.2: It is a view of the Group that the repository should not contain personally identifiable information. Verification systems should be used for preventing counterfeits, not for accessing individual patient/prescribing information.*

*4.3: Regarding repackaging. The Group have considered the scenario where repackaging uses several packs and has a quantity of drug left over and wish to raise this as a potential issue to be addressed. What would happen to the remaining stock when the process of repackaging is completed for a different pack size. For example if 4 packs of 30 are needed to generate a single pack of 100, what happens to the remaining 20?*

#### **D. CONSULTATION TOPIC N°4 - LISTS CONTAINING THE MEDICINAL PRODUCTS OR PRODUCT CATEGORIES WHICH, IN THE CASE OF PRESCRIPTION MEDICINES SHALL NOT BEAR THE SAFETY FEATURES, AND IN THE CASE OF NON-PRESCRIPTION MEDICINES SHALL BEAR THE SAFETY FEATURES**

**Identification criteria:**

- 1. Identification by Anatomical Therapeutical Chemical Code (ATC)**
- 2. Identification by brand name**
- 3. Identification by the name of the active pharmaceutical ingredient**

#### **4. A flexible approach on a case-by-case basis**

**Consultation item n°11: Which approach seems the most plausible from your view? Can you think of arguments other than those set out above? Can you think of other identification criteria to be considered?**

*Meeting the minimum requirements of the directive will only make the supply chain more complex and create further areas of risk and certainly will not address many of the concerns around the Patient. If only some selected products considered 'high-risk' require scanning by the pharmacy, this will add confusion and increase the likelihood that products will not be scanned. This needs to be implemented as a change in the dispensing process where all dispensed items are scanned at the point of dispensing.*

*From an implementation point of view, we believe that the most practical approach that provides the most benefits is that all medicine products should be scanned as they are dispensed. This should be irrespective of whether the pack has a unique serial number or not and should include unlicensed specials and parallel trade medicines. Unless every individual serialised pack is verified at the point of dispensing, patients will not benefit fully from the safety features. The unique serial number can only provide protection against counterfeits if it is routinely checked against a central database and the status changed on the database to 'dispensed' when the product is handed to the patient.*

*We believe that it will be very difficult for a decision to be made at the point of dispensing regarding which products require validation and which do not. The scenario could arise where a prescription is dispensed using one branded product and the other a generic alternative. In such a scenario it may be difficult to recognise which pack should be scanned leading to the wrong pack being scanned.*

*Consideration should be given to the implication of packs not being scanned as intended as this could have negative consequences on security of the supply chain and allow counterfeiting to continue.*

*The process of verification in the pharmacy should be virtually instantaneous in order to ensure efficient pharmacy workflow and the avoidance of delays. To ensure that products are verified in one scanning action, verification software should be integrated with existing pharmacy software. To ensure this process works efficiently, it needs to be built into working practice and is not onerous or time consuming to the pharmacy staff. This needs to be a simple and fast process to ensure patient's are not delayed in receiving their medicines.*

*The use of scanning technology each time a medicine is dispensed will help to minimise at least half a million undetected dispensing errors each year, that may cause patient harm and result in additional GP and A&E admission and hospital admissions.*

*The benefits arising from scanning every medicine as part of the dispensing process would be further enhanced by the planned full implementation of Electronic Transfer of Prescription technology in the NHS. This technology will help minimise transcription errors at the start of the dispensing system and bar code system will minimise physical dispensing errors at the end of the process.*

*Checking a unique, randomised, serial number placed on each pack against a central database at the point of dispensing is currently one of the most secure ways to verify product authenticity. However, a product verification system can only secure the content of the pack if it remains sealed at all times. Using tamper evident packaging makes it clear whether the pack has been opened or tampered with and is therefore an essential complement to a product verification system. Consideration needs to be given to the widespread use of 'part packs' in the UK. Where a single pack is used to fulfil more than one patient's prescription. How will the verification process operate for the second patients and how can authenticity be guaranteed where the pack is already open?*

*The cost of producing 2d codes on the labels produced in hospital pharmacy departments for over labelled patient packs may be an issue. This also raises the question of whether new codes would need generating for over labelled packs and if so how such codes relate back to that of the manufacturer. Furthermore who would maintain the database of the new codes and needs consideration.*

## **2. Applying the classification criteria**

**Criteria 1: Volume High volume: 5 points;**

**Low volume: 1 point**

**Criteria 2: Incidents in the EU or third country**

**Several incidents: 5 points;**

**No incident: 1 point**

**Criteria 3: Characteristic of the product**

**Characteristics indicate risk of falsification: 5 points;**

**Characteristics indicate no risk of falsification: 1 point**

**Criteria 4: Severity of the conditions intended to be treated**

**Conditions severe: 5 points;**

**Conditions not severe: 1 point**

**Criteria 5: Other potential risk to public health Max. 5 points.**

**On the basis of this scheme, it would be considered that:**

- **A prescription medicine which has 6 points or less is listed in the 'white list';**

- A non-prescription medicine which has more than 10 points is listed in the 'black list'.

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

*The Group believe that this is good starting point, however our view that verification applies to all medicines still stands.*

## **E. CONSULTATION TOPIC N°5 - OTHER ISSUES**

**1. Procedures for the notification of medicinal products from the national competent authorities to the Commission**

**2. Date of application of the delegated act**

**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.**

*Although the directive is focused on prevention of falsified medicines entering the supply chain (with all the accompanying negative consequences) the technology recommendation should acknowledge that the data carrier selected should be capable of meeting the wider requirements of the industry, the supply chain and health community and not just be limited to meeting the objectives of the Directive's requirements. In the absence of such a recognition there is a danger of introducing inefficiency and error into the whole process.*

*There is a real opportunity to utilise the likely technology solution to give benefits across the health sector that goes significantly beyond the pharmaceutical supply chain. This opens the possibility of an integrated infrastructure supporting the incorporation of single product identification with many other aspects of the health systems. We acknowledge that this is not an objective of the directive but it shouldn't exclude the possibility of aiding in its delivery.*

*Linear bar codes have been placed on the majority of medicine packs in the UK for nearly twenty years. These bar codes are very seldom used in practice in primary care and only a small percentage of hospital pharmacy dispensing uses this technology at the point of dispensing. There has been poor benefits realisation from this technology. There is a risk that additional resources will be spent on including anti-counterfeiting technology on medicine packs to comply with the new EU Directive and this technology will similarly not be used in practice in the future with little or no benefit to patients. It is essential that there are sufficient benefits for health professionals and their patients to ensure that that the technology is used in day to day practice.*

*Any proposal should not be so prescriptive that it limits the use of other innovative technology to deliver the requirement or drives the requirement down a technological cul de sac.*

*The Group believe that the primary benefit from implementation of these measures will be to patient safety but by taking a balanced view alongside the economic benefits we are much more likely to end up with a solution that all parties can commit to.*

*By scanning unique code and using the information contained therein, in tandem with electronic health records, patient safety and outcomes will be improved. Errors in supply and administration will be minimised through the validation of correct clinical use and ensuring that product selected from the shelf, is correct, authentic and safe. Of the 526,379 reported NPSA medication alerts, it is the view of the Group that half of these would be avoided with implementation of product verification using 2d coding.*

*We believe that there are significant benefits to be had to the medicines recall proces and success rates. Being able to easily trace dispensed medicine linked to the batch number back to an actual patient will significantly improve the product recall process and make the process faster and more efficient.*

*Efficiency Savings are envisaged across the supply chain through improved visibility of stock throughout the supply chain, providing benefit to manufacturers, wholesalers and hospitals stock management systems and will reduce the impact of counterfeits from entering the supply chain.*