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

Details on Domino

Founded in 1978, Domino printing sciences has a global reputation for the development and manufacture of coding, marking and printing technologies that satisfy the compliance and productivity requirements of manufacturers. Domino's consistent year-on-year growth – both organic and through acquisition – is underpinned by an unrivalled commitment to product development, resulting in a portfolio that incorporates complete end to end coding solutions spanning primary, secondary and tertiary applications. Innovative ink jet, laser, print & apply and thermal transfer overprinting technologies are deployed for the application of variable data, bar codes and unique traceability codes onto product and packaging, across many industrial sectors, including food, beverage, pharmaceutical and industrial products.

In 2009 Domino (Domino Printing Sciences plc) achieved a turnover of £256.1m million; it is listed in the FTSE 250 share index on the London Stock Exchange (share code DNO). Domino employs 2,000 people worldwide and sells to more than 120 countries through a global network of 25 subsidiary offices and more than 200 distributors. Domino's manufacturing facilities are situated in China, Germany, India, Sweden, UK and USA.

For further information on Domino, please visit www.domino-printing.com

Domino Printing Sciences is the leading supplier of coding and marking systems to the Pharmaceutical sector and has been working closely with most of the early adopters in the use of unique coding in as a means of delivering verification and authentication within the pharmaceutical supply chain.

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?

Domino have a strong preference for Policy Option 2 as 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 Domino that use of 2D data matrix, including the product's GTIN, expiry date, batch number and unique serialisation number, should be implemented to GS1 standards.

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. Enabling the identification of individual packs at the point of dispensing has huge advantages to patient safety and anti-counterfeiting.

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.

Domino have a strong preference for both data elements to be included in the pack code. The ability to automatically machine read this data would be of huge benefit to patient safety through the use of this functionality.

Using 2D bar codes to enable individual serial numbers and allowing batch number and expiry date information to be available electronically at the point of dispensing. This will significantly improve the ability to track batch numbers supplied to individual patients and enable both batch recalls and alerts if expired or short date stock is about to be dispensed.

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.

Domino believe that there needs to be a clear differentiation if re-imbursement information is included in the code.

2.2. Regulation of the technical characteristics of the carrier

2.2.1. Linear barcode

The length of barcode needed to carry all the additional data elements; such as batch number, expiry date and serialisation codes would make the barcode too long for linear codes to be a viable option for dispensed medicines.

2.2.2. 2D-Barcode

2D carriers are able to carry all the necessary data elements in a code which could be applied to a medicine label without significant compromise.

The only 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 as well.

2.2.3. Radio-frequency identification (RFID)

RFID is the most expensive option and we do not believe this is necessary for use on medicines as sufficient information can be contained within 2D barcodes at a much lower cost with a much higher rate of readability.

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 Domino 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: Domino has no comment on this area.

Policy Option 2: Domino has no comment on this area.

Policy option 3: Domino has no comment on this area.

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).

Domino have a preference for the stakeholder governance of the repository.

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.

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 Domino that the repository should not contain personally identifiable information.

4.3: It is key that the re-packaging of medicinal products is managed under the same umbrella of the governance of the repository. The system should ensure that the process is identical whether it is originally manufactured product or repackaged product.

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?

A flexible approach should be taken here, however, it is the strong view of Domino that all medicinal products should be validated at a minimum 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.

It is worth considering that a product verification system can only secure the content of the pack if it remains sealed at all times therefore using tamper evident is an essential complement to a product verification system.

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.

Domino believe that this is good starting point, however it is our view that verification should apply to all medicines.

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 wider requirements of the industry.

As well as the befits to patient safety efficiency savings are envisaged across the supply chain. The 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.