**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**

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Contribution to be made public on the European website (pharmaceuticals)

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### 4. CONSULTATION TOPIC N° 1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

#### 2. Policy option n°1: Leaving the choice to the individual manufacturer

**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?

<table>
<thead>
<tr>
<th>Preference for option 2</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Would ensure standardisation</td>
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<tr>
<td></td>
<td>Enables transparency and common understanding of what is required.</td>
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<td></td>
<td>Would result in more accurate data as processes for data entry would be similar</td>
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</table>

**Disadvantages**

- Reduces the scope for individual initiatives and may result in less than optimal implementation; however, the benefits of harmonisation through regulations are perceived to be much greater than the possible top-end adoption of a minority, which would inevitably lead to inequality in implementation.

#### 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.

**Advantages**

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

**Disadvantages**

- Additional product information
- Expiry date
- Batch number

**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.

**Advantages**

- Batch number and expiry date are necessary. This information can be accommodated using 2D barcodes.
- While it is possible given a unique batch number to access its expiry date on a remote server, in connection may not always be possible. Often the expiry date is imprinted on packaging that is discarded. Having this information in a barcode would ensure medication that has deteriorated is never administered to patients.
- The need for batch number is essential for recall of products and identification for products where there is significant variation of efficacy between batches.

**Disadvantages**

- There is more information held on the barcode, however, this can readily be accommodated with a 2D system.

#### 2.2. Radio-frequency identification (RFID)

**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?

**Advantages**

- RFID has the greatest capability for holding information and in automation of manufacturing and dispensing processes, however, costs with the current technology are not warranted at this time as there are no clear effective current solutions.
- RFID has the greatest capacity for holding information and in automation of manufacturing and dispensing processes, however, costs with the current technology are not warranted at this time as there are no clear effective current solutions.
- The unique identification of unit of use would enable additional functions.
- The NPSA asks that the unique identification code is additionally required on the 'unit of use'.

**Disadvantages**

- The UK does not use the re-imbursement number. If this were implemented it would require dedicated software systems and additional expense to map the number to existing systems. Manufacturers will be required to assemble greater information.
- While we accept there will be additional printing costs for unit of use, the technology now exists for extending and printing labels even for small products such as ampoules.

#### 2.3. 2D-Barcode

**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 points for each concept? Please quantify your reply, wherever possible, by listing for example:

- Costs for adapting packaging lines of medicines packaged for the EU market.
- Costs for reading devices for the different carriers.
- Costs for additional printing costs for unit of use, the technology now exists for extending and printing labels even for small products such as ampoules.

**Preference for option 2**

- The abovementioned serialisation number includes the national reimbursement number. In this case, the serialisation number could be composed as follows:
  - Manufacturer product code (which includes the prefix of the country)
  - Expiry date
  - Batch number

**Advantages**

- Enables transparence and common understanding of what is required.
- Would result in more accurate data as processes for data entry would be similar.

**Disadvantages**

- Reduces the scope for individual initiatives and may result in less than optimal implementation; however, the benefits of harmonisation through regulations are perceived to be much greater than the possible top-end adoption of a minority, which would inevitably lead to inequality in implementation.

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### 5. CONSULTATION TOPIC N° 2: POSSIBILITIES FOR THE UNIT OF USE

**Preference for option 1**

- Systematic check-out of the serialisation number at the dispensing point

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

**Preference for option 2**

- As in policy option n°1/1, but with additional random verifications at the level of wholesale distribution

**Preference for option 3**

- As in policy option n°1/1, but with additional systematic verification by the wholesale distribution
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. Please quantify your reply, whenever possible. This applies in particular to the

Policy option n°1 – EU governance

Policy option n°2 – national governance

Policy option n°3 – ‘stakeholder governance’

Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, whenever possible. This applies in particular to

Policy option n°4 – EU governance

Policy option n°5 – national governance

Policy option n°6 – ‘stakeholder governance’

Policy option n°7 – EU governance

Policy option n°8 – national governance

Policy option n°9 – ‘stakeholder governance’

Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, whenever possible. This applies in particular to

Policy option n°10 – EU governance

Policy option n°11 – national governance

Policy option n°12 – ‘stakeholder governance’

Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, whenever possible. This applies in particular to

Criteria 1: Volume

High volume: 5 points;

Low volume: 1 point

Criteria 2: Date of application of the delegated act


Criteria 3: Incidents in the EU or third country

No incident: 1 point

Criteria 4: Severity of the conditions intended to be treated

Severity not severe: 1 point

Severity severe: 3 points

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’.

Identification criteria in the UK the default should be the MHRA/EMEA accepted Summary of Product Characteristics designation.

In summary the technology that is being proposed to help minimise the risks from falsified medicines will become part of routine clinical practice and provide additional benefits of ensuring the correct product is selected and reducing dispensing errors.

1. Although the directive is focused on prevention of falsified medicines entering the supply chain (with all the accompanying negative consequences) for the proposed technology to be widely adopted in practice the adoption will also help to reduce dispensing errors as well as identify falsified medicines. The use of 2D bar codes on medicine packs can also help to reduce administration errors on administration. It is essential that the use of this technology is seen to achieve a wider range of patient safety benefits and not be restricted to only reducing risks of falsified medicines.

Policy option n°10

Wholesalers could provide verification; however, there may be opportunities after distribution for counterfeit products to enter the system bearing the same packaging.

Policy option n°11

The NPSA advises Policy option n°10 – EU governance. This is necessary as medicinal products are manufactured and distributed on a world-wide basis. The costs borne by manufacturers are only sensible if applicable to EU setting. There are significant inefficiencies if every member country was to negotiate specific containment policy measures. Each member state would negotiate containment policies for each medicinal product.

Policy option n°12

A flexible approach on a case-by-case basis.

Policy option n°13

The naming, labelling and packaging of medicine products is complex and subject to human error. It is essential that new technology provides a means to reduce human error and conform the identity and the authenticity of the medicine product before it is dispensed and used.

Policy option n°14

Information that identifies the act/action of cancelling and order if an error had been made in the supply of the product; for example a look alike, sound like selected error has been made should be accessible. This is a major source of error in prescribing, dispensing and administering of medicines.

Policy option n°15

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’.

Identification criteria in the UK the default should be the MHRA/EMEA accepted Summary of Product Characteristics designation.

Policy option n°16

- A framework for the掩饰 the full consequences of the directive to the national competent authorities to the Commission.

Policy option n°17

- A framework for the掩饰 the full consequences of the directive to the national competent authorities to the Commission.

Policy option n°18

- A framework for the掩饰 the full consequences of the directive to the national competent authorities to the Commission.

The only practical approach is for all medicine products to be scanned prior to being dispensed. This will then become part of routine clinical practice and provide additional benefits of ensuring the correct product is selected and reducing dispensing errors.