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 Europa website (pharmaceuticals)

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?**	Preference for option 2 **Benefits** Would ensure standardisation Enables transparancy 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 regulationis are percieved 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** Having both the manufacturer's product code and the pack number facilitates identification during product recall. Also for biotechnology drug and biosimlars individual packs vary in their immuniogenicity and therapeutic outcome. Tracking this is only possible if pack numbers are included. The pack number must be communicated to unit of use as packaging is often discarded prior to administration. **Disadvantages** There is no perceived disadvantage to having both the manufacturer's product code identifying the specific characteristics of the product and the pack number identifying specifically the drugs for administration.
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.**	**Advantages** Both batch number and expiry date are necessary. This information can be accommodated using 2D barcoding. While it is possible given a unique batch number to access its expiry date on a remote server, a connection may not always be possible. Often the expiry date is imprinted on packaging that is discarded. Having this information on unit of use and available at adminstration ensures medication that has deteriorated is never adminsistered 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.
(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 NPSA advises a preference for Option 2. **Benefits** So long as it is possible to accurately identify the re-imbursement number from the serialiastion number and other information, then there would be no disadvantage to UK adoption of Option 2. For EU use this option would allow countires that have adopted reimbursement systems to continue such use. 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', such as individual ampoules. It is common practice for nursing staff to discard packs thus severing the continuity of the identification process.By requiring identificaiton by unit of use we can be assured that patients are adminsitered the correct and ligitimate product. **Disadvantages** The UK does not use the re-imbursement number. If this were implemented it would require dedicated software systems and additional expence to map the number to existing systems.Manufactdurers 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 on labels even for small products such as ampoules.
2.2. Regulation of the technical characteristics of the carrier 2.2.1. Linear barcode 2.2.2. 2D-Barcode 2.2.3. Radio-frequency identification (RFID) **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.**	2D carriers will provide the necessary information, are readily implemented to 'unit of use' and are the most cost effective current solution. **2.2.1** It is possible with the linear barcode to additionally provde patient safety functions; however, the inclusion of a national reimbursement number, serialisation code, batch and expiry information on a label suitable for such as an ampoule would necessitate such fine detail that current barcode readers may not be able to accurately scan information. Thus, we would advocate the 2D barcode is adopted. **2.2.2** While the implementation of 2D is more expensive as it necessiates changes to printers and more expensive scanners, the 2D barcode is capable of carrying all the necessary data elements in a code which could be applied to a product label without compromise. The cost of RFID is a current barrier to implementation and we would advocate adoption of the 2D barcode. **2.2.3** 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 advantages over 2D barcodes for the necessaary patient safety functions.
B. CONSULTATION TOPIC N° 2 - MODALITIES FOR VERIFYING THE SAFETY	
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 n°2/1** This in our opinion is the only practical option. In our view 2D bar codes are required at unit of use and on the outer pack of all medicines. All medicine packs should be scanned at the point of dispensing to minimise 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 range of patient safety benefits and not be restricted to only reducing risks of falsified medicines. **Policy option n°2/2** There is little or no information to base the probability of failing to identfy an incorrect product should a random verification process be implemented. We strongly suggest this is not adopted. **Policy option n°2/3** Wholesalers could provide verification; however, there may be opportunities after distribution for conterfeit products to enter the system bearing the same packaging.
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 NPSA advises Policy option n°3/2 – EU governance. This is necessary as medicinal products are manufactured and disseminated on a world-wide basis. The costs born by manufacturers are only sensible if applicable to an EU setting. There are significant inefficinecies if every member country was to negotiate specific presentations of each manufacturers' products (Policy option n°3/1).
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?**	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-alike select error has been made should be accessable. This is a major source of error in prescribing, dispensing and administering of medication.
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?**	Tracking and tracking of medication must be transparent and able to mantain a link if medical products are re=packaged. If this is not the case then the validity of verification would be in doubt.
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	
1. Identification criteria: Identification by Anatomical Therapeutical Chemical Code (ATC) Identification by brand name Identification by the name of the active pharmaceutical ingredient 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?**	The naming, labelling and packaging of medicine products is complex and subject to human error. It is essential that new technology provides a means reduce human error and conform the identity and the authenticity of the medicine product before it is dispensed and used. Identification criteria in the UK the default should be the MHRA/EMEA accepted Summary of Product Characteristics designation.
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 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.**
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.**	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 at the point of dispensing, the same technology should be used improve other important risks to patient safety. There is good evidence that dispensing errors occur frequently and death and serious harms result from miselected medicines. The use of 2D bar codes technology every time a bar codes is dispensed can significantly reduce dispensing error as well as identify counterfeit medicines. Further more the use of 2D bar codes on medicines at unit of use level will enable this technology to be used when administering medicines to patients will help reduce medicine administration errors. The EU Directive will be more successfully implemented in clinicsal practice if it is addresses a broader range of important patient safety issues rather than a single focus of falsified medicines. 2. 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. 3. The primary benefit must be patient safety in terms of ensuring what is prescribed is dispensed and adminstered is the intended product. 4. Use 2D data matrix GS1 Code carriers for GTIN; ,Expiry Date, Batch Number and Serialisation Number printed on the presentation pack, and where necessary the unit of use if the pack is likely to be discarded during normal practice. 5. Omission of medication due to lack of availability is an ongoing concern.Use of barcoding as described faciliates stock control and strengthens the supply chain. This would lead to greater control over a difficult aspect of service provision. 6. The act of scanning provides multiple verifications to confirm that the medicine is not falsified and that the right product is being dispensed and administered or given to the right patient. It will ensure that consistant information is fed into the healthcare system and enable healthcare practitioners to confirm and validate their actions against accurate information. **In summary the technology that is being proposed to help minimise the risks from falsified medicines will also help to minimise dispensing and medicine administration errors and it essential that recognition to these other important risks to patient safety is included in this directive to ensure that clinical practitioners fully participate in using the new technology to minimise risks and improve patient outcomes**