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

**Comments from the Czech Republic**

## 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?**

Option n°1/2: harmonisation through Regulation should be preferred. The EU needs a uniform system in order to meet all requirements set out in Directive 2011/62/EU. Different technical specification would result in higher costs for verification and inclusion of additional functions of the safety feature would become difficult, if not impossible. System under option 1/1 would bring only limited improvement against the existing state of play.

### 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.**

In general, we agree with the proposed basic structure of the unique identifier (product code, pack number).
Additional data (batch number, expiry date) will definitely improve the system´s speed and efficacy; therefore we suggest that both are included.
NHRN (National Healthcare Reimbursement Number) could be either included in the safety feature (Option 2) or accessed through linking to a data repository.

A number of manufacturers in the pharmaceutical industry already use the global GS1 system for product identification and this system appears to be sufficiently robust, reliable and having potential to include also additional data beyond the requirements laid down by the directive. It can be assumed that by the time of application of the delegated act (2017) the technical progress will allow for a cost-effective solution.

### 2.1.2. Additional product information

**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.**

Machine-readable batch number would facilitate distribution and traceability and in case of suspected falsified products or quality defects the recall would be significantly easier. Given that under Article 80(e) of Directive 2001/83/ES wholesale distributors are required to record the batch numbers of, as a minimum, all medicinal products with safety features, automatically readable batch numbers would facilitate recording and eliminate human errors.

Inclusion of expiry date would be also of benefit both for wholesale distributors and pharmacists. We agree that it may facilitate storage management and enhance patient safety. However, even if these data are included in the safety feature they must be also printed in a human readable format as the patients and healthcare professionals need immediate access to this information without any scanning device.

**National reimbursement number**

**Consultation item n°4: Which of the two options set out under point (c) of point2.1.2 is in your view preferable? Where do you see advantages and disadvantages? Please comment.**

Both options are acceptable. It is not necessary to incorporate the national healthcare reimbursement number (NHRN) in the serialisation number, it may as well be stored in the repository and linked to the safety feature.

In the Czech Republic the NHRN ("SUKL code") is assigned by the State Institute for Drug Control to each presentation of the medicinal product and is used both for reimbursement purposes and tracking and statistical evaluation in compliance with regulatory requirements.

It is obvious that inclusion of the NHRN places higher requirements on technology and logistics as each national market must have a different version of the safety feature.
Within the GS1 system it is possible to associate the NHRN with the global GTIN identification number within database systems and data carriers (e.g. GS1 Barcodes) in a GS1 compliant way. This will allow, where necessary, a GTIN and national number to be held in the same bar code symbol so that both can be captured with a single scan. Like all other GTIN attribute Application Identifiers, the NHRN AI must always be used in combination with a GTIN.

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

**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?**

1. Linear barcodes may carry only a limited amount of data compare to the other two options. Considering the necessary area of the packaging and intended amount of information we find this system inappropriate and outdated.

2. 2D-barcode appears to be the most suitable option for the intended purpose. Its size may be adapted also to small-size packaging and it is able to carry sufficient amount of information. The requirements on printing and scanning technology are not excessive and should be affordable even for small businesses. Considering the deadline for introduction of safety features which is expected to be 2017, it is assumed that technical progress will allow for reduced costs and effective use. Also the end-users may have access to the defined range of information through user-friendly and easily available applications in their PCs or smart phones.

3. RFID due to higher costs it is not suitable for routine use.

## 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?**

Under the Czech law, certain medicinal products may be dispensed also by healthcare professionals. This applies to vaccines, blood products and radiopharmaceuticals. Some medicinal products may be supplied directly to healthcare establishments (solutions for infusion, vaccines etc.). If such products are subject to safety features the above mentioned dispensing points would have to comply with the requirements laid down in delegated acts unless a special secured channel or other provisions are in place.

Another issue to be addressed is the cross-border internet sale of medicinal products which are subject to different rules in member states: an OTC product may be classified as POM in the member state of destination and should thus be subject to safety features even though in the member state of origin this requirement does not apply.

**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.**

Systematic check-out at the dispensing point provides for the minimum level of patient protection. Therefore, **option 2/1** is considered the minimum acceptable standard. However, we find it inappropriate to perform check of safety features as late as at the dispensing point because potential problems would be solved in the presence of patients and that would not contribute to patients' confidence in medicinal products.

**Option 2/2** is a reasonable standard; however, some rules for random verification should apply. This includes risk management based on risk analysis to identify the bottlenecks of the distribution chain and establish what products should be subject to more intensive control. Criteria may include e.g. previous incidents of falsification, none or short history of cooperation with a particular supplier or carrier company, non-standard appearance etc.

**Option 2/3** provides the optimum level of protection of the market and patient safety and **should be preferred**. Safety features should be checked upon receipt and picking/supply to another distributor or healthcare establishment. Systematic control would allow for making full use of the potential for additional information linked to the safety feature.

Besides systematic verification throughout the distribution chain also optional verification on the patient level could be available, e.g. through smartphone applications capable of reading 2D barcodes. The scope of data accessible to the patients as well as individual actors in the distribution chain must be defined.

Currently there are approx. 7600 medicinal products marketed in the Czech Republic, out of which 5200 are reimbursed. We have 382 licensed wholesale distributors and more than 2500 pharmacies, about 12% pharmacies hold also a wholesale distribution licence.

## 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).**

**Option 3/1**, stakeholder governance, raises concerns that competent authorities will not have appropriate control over the system. It is the responsibility of the Member States to ensure that the system is safe and functional; therefore we do not support this option.

**Option n°3/2**, a pan-European repositories system, is preferred. Although the storage and management of a large amount of data and connection of all actors to one system is challenging its benefits are obvious and also the costs would be lower than for national systems. Private cloud technology with distributed repositories can be used.

**Option 3/3**, national repositories, requires high initial costs and the requirements on capacity are difficult to estimate. We assume that the amount of information stored within the next 10 years will increase 44 times. Interconnection would present a challenge and from the point of view of manufacturers and distributors operating in more Member States this option would mean duplication of work. In particular, small markets would face problems with this option and regional repositories would probably be preferred anyway.

### 4.1. Information of a commercially sensitive nature

**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?**

As mentioned above, the system is capable of monitoring all operations performed during wholesale distribution where scanning is included, tracking the product from the manufacturer up to the patient. If policy option 2/3 is chosen for verification the delegated act should clearly define the rules for access from individual levels and data ownership.
This issue is linked to the safety of data storage in general. Safety standards must be clearly defined and observed with regard to cybernetic and information security, energy supply, physical access, staff and administrative safety etc., starting from setting the basic safety policy up to the routine control of compliance with safety standards, evaluation and taking action where necessary.

**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?**

The same principles as for point 4.1 should apply.

## 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

In general, we hold that identification of products that shall bear the safety features is the most challenging point of the anti-counterfeiting strategy. The Consultation Paper states that for the purposes of ascertaining whether a medicinal product is subject to prescription, the relevant territory is the Member State where the product is intended to be made available to the final user. However, this may result in significant complication for the manufacturer as the same product marketed in more Member States or different package sizes of the same product in one Member State may be subject to different rules. As the Consultation Paper points out, Member States may also require labelling of the unique identifier on any prescription-only or reimbursed medicinal product, irrespective of the list.
Moreover, before final decision is taken on the lists of products that must or must not bear the safety feature, consideration should be given whether it is worth to invest in a complex system of repositories for a limited number of products. The costs will not be significantly lower if the safety features apply only to products at high risk and other benefits linked to the additional data may be lost. Obviously, the more data are accessible through the system the better value against costs is achieved.

**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?**

We suggest that identification should be based on the brand name

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

The proposed weight of criteria and method of evaluation suggest that vast majority of prescription medicinal product will fall within the scope of safety features, making in fact classification for supply the only criterion. This is in line with Article 54a; however, recital 11 of Directive 2011/62/EU presumes that certain categories of products, e.g. generics, will be excluded. We believe that classification criteria should be discussed on expert level before any draft delegated act is submitted. It is not clear e.g. how volume should be quantified taking into account small and big markets.
We doubt that point value from 1 to 5 for each of the proposed criteria is optimal and can best serve the purpose. Assignment of points will require a special methodology (to determine the appropriate number of points). Another option that may be considered is keeping the proposed list of criteria and setting the point value at 0 or 1. In order to bear mandatory safety features the minimum result for a medicinal product would be 3 points. For certain criteria the value

may range from 0 to 2 (0 – criterion does not apply, 1 – medium value, 2 – full compliance). In that case the sum of 3 may be replaced with a higher value depending on the number of criteria with extended range 0, 1, 2. E.g. if two criteria are in this group, the minimum result would be 5.

On the other hand, there are practical reasons to support the concept of a unique identifier for any reimbursed or prescription medicine, or even for medicinal products in general, see discussion above. In this context we would like to draw attention to Article 3 of Directive 2011/62/EU requiring that within five years from application of the delegated act the Commission shall submit a report containing, among others, the evaluation of the contribution of safety features to the prevention of falsified medicines.