Comments on

European Commission`s Concept Paper on Delegated Act for a Unique Identifier etc. from Nov. 18, 2011

A. CONSULTATION TOPIC N°1:

CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

CONSULTATION Item 1-5

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Content:

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No.	Subject: Technical Specification	
	Consultation item n°1:	
	Policy option n°1/1: Leaving the choice of the technical specification to the individual manufacturer	
	Policy option n°1/2: Harmonisation through regulation	
1	Option 1.2 - Benefits	We favour the policy option no. 1/2 “Harmonisation through regulation” (page 5 of the paper), the benefits are already enumerated in the concept paper.
2	**In this application, it is necessary to view the different functional levels with their differing harmonisation requirements. Therefore we wish to submit proposals according to the levels as below:**	
3	Option 1.2 - Comment Harmonisation Level: Data for Verification	The verifiable data content, to be used in the databases, should be harmonised throughout Europe.
4	Option 1.2 - Comment Harmonisation Level: Syntax	The syntax to be used should be based on the international standard ISO / IEC 15 434 "Information technology - Automatic Identification and data capture techniques - Syntax for High-capacity ADC media".
5	Option 1.2 - Comment Harmonisation Level: Structure	Allow the use of standardised Application Identifier (AI) and Data Identifier (DI) with the associated system identifiers according to ISO / IEC 15418/ANSI MH10.8.2 "Information technology - Automatic identification and data capture techniques / Data Identifier and Application Identifier Standard" within the data carrier.
6	Option 1.2 - Comment Harmonisation Level: Data Carrier	The regulations should be based on the international ISO and / or European CEN standards.
7	Option 1.2 - Harmonisation Level: Data Carrier	The data carrier specification should be flexible enough to take advantage of future technological enhancements.
8	Option 1.2 - Comment Harmonisation overall	Committing to the specification of just one commercial operator or user group leads to a distortion of competition. Critical are the use of: - single proprietary specifications - specifications which promote the commercial interests of a service or a product

No.	Subject: 2.1.1 Manufacturer product code and pack number **Consultation item n°2:**	
9	General remark	In point 2.1 and 2.2 the use of the terms “serialisation number” (# 20 to 30) and “unique identifier” (e.g. # 21, 26) are misleading. In several cases, the term “serialisation number” is used when referring to the complete data content of the code, in other cases (e.g. # 12, 13, 15), serialisation number” is used where actually the term “unique identifier”, in the sense of a combination of „Product code“ and „Individual pack number“ is meant. In this context, we suggest, in order to differentiate it from other product groups e.g. medical devices referred to as “Unique device identifier (UDI)”, that the term be expanded to “unique medicinal product identifier (UMI)”. We request that this explanation should be incorporated in the Delegated Act. Furthermore the corresponding terminology of the standards ISO/IEC 19762 Part 1 + 2 should be applied.
10	Option 2.1.1 - Disadvantages	In regard to consultation item no. 2 we disagree with the approach as set out in point 2.1.1.
11		A country prefix is not necessary for verification. The reference is also potentially ambiguous. The definition of the country prefix is inexplicit. What is meant - the country of manufacture or the country of sales? The international uniqueness of the product code is of paramount importance.
12		The "Manufacturer product code" proposed is unnecessarily restrictive. Up to now no "Manufacturer code” has been established (in Germany and other countries e.g. Austria, Belgium, France, Italy, Portugal, Spain) and is therefore not applicable. There should be an internationally unique product code that is generated either by the manufacturer or by a national registry. The introduction of a new "Manufacturer product code" would add a high burden on Europe's healthcare system.
13		The guidance document referred to in paragraph 21, footnote 16 quotes the optional use of the GTIN as a product code. Commitment to the use of a fee-based use of a single (monopoly) organization should for competitive reasons be disallowed.
14	Option 2.1.1 - Proposal	The proposed "Manufacturer product code" should not be used. A unique product code is sufficient. References to the country or the manufacturer are not mandatory. Recommendation for differentiation and at the same time harmonisation of various existent product codes - refer to Appendix 1

No.	Subject: 2.1.2. Additional product information; (c) National reimbursement number **Consultation item n°4:** **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:**	
15	Option 2.1.2 (c) Option 1 Disadvantages	Situation in Germany: Reimbursement systems require the use of the national product number PZN as anchored in legal statutes and implemented in all systems.
16		Higher costs (databases) and administrative effort and expense for the changeover process from the national product code to another international product code.
17		Long transition periods would be required. Approx 10 years, with the negative consequences: - Parallel existence of two product identifications in a long transition period. - Increased complexity, risks associated with the ambiguous declaration of the products in this transition period.
18	Option 2.1.2 (c) Option 2 Disadvantages	Scenario for the German market: Two parallel product identities (Manufacturer product Code *) and national reimbursement number) would exist in the market. This would mean: - Additional costs of maintaining two product identifiers; - Additional costs due to double license fees for the product codes. - Potentially additional costs due to higher volume of data (increased code size) - Risks, since both "Manufacturer product code" *) and "National Reimbursement Number" are the primary key, depending on the application. Potential error source through use of the wrong primary key. - Potential error through inaccurate timing of synchronisation during the update of the product code. - Increased complexity in two parallel existing product codes. *) General remarks about the "Manufacturer product code", refer to comments Item No. 9 and 12.
19	Option 2.1.1 - Proposal	Open standard for worldwide unique "Product code" introduced, while retaining the existing identification systems such as GS1, HIBC, IFA, ISBT, VAT and Eurocode IBLS. Refer to proposal in Appendix 1
20		"National Reimbursement Numbers", which currently are not internationally unique, the integration in the "Pharmacy Product Code" could be used, as described in Appendix 1.

Attachment 1:

Proposal "Product Code"

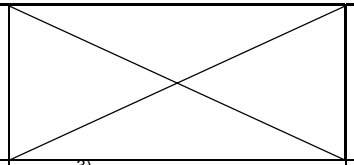
belongs to Consultation item no. 4, Option 2

Recommendation for differentiation and at the same time harmonisation of various existent product codes

Attachment 1

Proposal 1: - Product Code includes national reimbursement number:

This proposal should amend the table in Consultation item n°4, No. 29 as following:

Product code (which includes the national reimbursement number) [1)]	Unique identification number of the pack (Individual pack number) [2)]		Expiry date (see point b)	Batch number (see point a)
XXXXXXXXXXXXXXX	XXXXXXXXX	----- [3)]	XXXXXX	XXXXX

Explanations:

1) For example GTIN, NTIN or PPN

2) Notion refer to comments Item No 9

3) does not apply, National reimbursement number is contained in the Product code

"Unique Medicine Identifier" for Verification

Optional – not relevant for Verification

Benefits:

- No redundancies, no references,
- Perpetuation of existing numbers
- Avoids errors

Attachment 1

Proposal 2: - Pharmacy Product Code includes the International Product Code and the National Reimbursement Number

This is the preferred proposal and should amend the table in Consultation item n°4, No. 29 as following:

Pharmacy Product Code (Pharma-Prefix [1),2)] + Existing product code [3)])	Unique identification number of the pack (Individual pack number) [4)]		Expiry date (see point b)	Batch number (see point a)
XXXXXXXXXXXXXXXXX	XXXXXXXXX	----- [5)]	XXXXXX	XXXXX

Explanations:

1) This new Prefix could be assigned by an independent European institution

2) Notion refer to comments Item No 9

3) National reimbursement number (e.g. PZN, AIM, CIP) or international product code (e.g. GTIN, NTIN)

5) does not apply, National reimbursement number is contained in Pharmacy Product Code

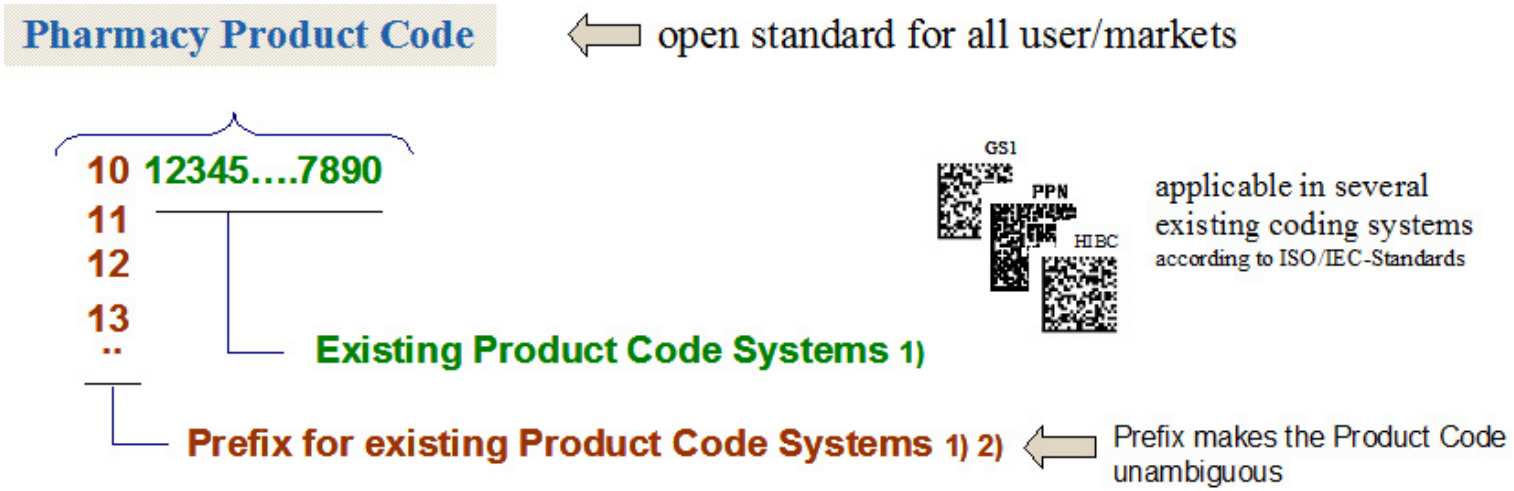
"Unique Medicine Identifier" for Verification

[2)] Further details how to create the Pharmacy Product Code see next page

Benefits:

- Reduces complexity and costs in data bases
- No redundancies, no references,
- Avoids errors
- Perpetuation of existing numbers
- Cost effective
- No change of established processes
- Perfect base for verification systems
- No additional licence fees
- Parallel use of any national reimbursement number
- Open for any coding system (GS1, IFA, HIBC, …)

How to create the Pharmacy Product Code



1) Product Code Systems: e.g. GTIN/NTIN or NATIONAL REIMBURSEMENT NUMBER (PZN, AIC, CIP, ……..)
2) Prefix could be assigned by independent European Institution