EHIBCC

To: European Commission
Unit SANCO/D/3,
BREY 10/114,
BE-1049 Brussels.

Date: 12 april 2012

Ours: EHIBCC-Avz 120412

Subject: CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION:
DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION
Brussels, 18/11/2011, Sanco.ddg1.d.3(2011)1342823

Dear Unit SANCO Team,

As a stakeholder association and on behalf of our members we would like to respond to the concept paper on RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION.
Our members are marking medical and medicinal products uniquely since the mid 90ths and have great experiences in it. EHIBCC is maintaining the Health Care Industry Bar Code (HIBC) and contributing actively to the standardization projects on CEN and ISO level. We are of the opinion, that the CEN and ISO platform are the best base for building IT systems enabled by Automatic Identification. We would like to offer our contribution to EUropean solutions which are fully conforming to current standards and its updates achieving the goal by help existing bases.
This in order to minimize costs and to optimize the functionality.

Please don't hesitate to contact me any time for UID matters and I will do my best to contribute on behalf of our members and users.

Best regards

Greetings,
A van Zijl, Chairman EHIBCC

Attachment: Comment

European Health Industry Business Communication Council - EHIBCC
Jozef Israelslaan 3
NL-2596 AM The Hague, The Netherlands
Tel.: +31 703244754
www.ehibcc.com

EHIBCC Technical Committee
Kösener Str. 85
06618 Naumburg, Germany
Tel.: 03445 781140
www.hibc.de

Rev. 2012-0403

Comments to the
CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION:
DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION
Brussels, 18/11/2011, Sanco.ddg1.d.3(2011)1342823

The Technical committee of EHIBCC would like to comment to the paper to bring in long term experiences with automatic identification and unique product marking. EHIBCC is a member association where the majority of members are manufacturers for medical devices but some members manufacture or trade medicinal products as well. In addition to it we liaise with pharmaceutical companies and associations and with hospitals to global issues of uniqueness and interoperability. In countries, like The Netherlands, HIBC is in active use also for marking Medicinal Products successfully. We would like to recommend taking into account the result of the public consultation of the Global Harmonization Task Force - GHTF and the resulting paper *"GHTF/AHWG-UDI/N2R3:2011, Unique Device Identification for Medical Devices"*. The paper achieved interoperability not only between different UID constructs but also with different product ranges as medicinal products, medical devices, specific equipment and consumer products based on globally and nationally agreed standards where CEN and ISO standards are in the focus and GS1 codes and HIBC codes as part of it. We recommend to join the international standardization processes with CEN and ISO taking the load from the legislation to specify the technical details. For UIDs this has been done with standards already, like *ISO/IEC 15459 Unique Identification and application* standards for Barcode like ISO 22742 Linear and 2-dimensional symbols for product packaging and for optional RFID with ISO 17366 RFID for product tagging. We see the important role for the EUROPEAN COMMISSION, HEALTH AND CONSUMERS DIRECTORATE-GENERAL for creating the framework to be fulfilled by the stakeholders for health systems and health products. We trust, that the DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION will consider common practices and experiences of automatic identification methods running in an interoperable way cross products and cross country and that the EC will not allow monopoly for specific systems limiting or causing unnecessary changes and costs. We are in favor of the most efficient system in terms of cost, functionality, safety, which is a system with ONE reference number only. We are in favor of a "ONE UID" system which can be the National Reimbursement Number (NTN), the manufacturer product number or the number the national legislation may require. We are not in favor of a system which requires constructs consisting of two UIDs or numbers where one might be the NTN and the other the manufacturer's code to be processed in parallel. The TC being in active co-operation with CEN TC 225 and ISO/IEC JTC 1/SC 31 for standardization of AutoID and for updates and maintenance of the standards will be pleased for any expert question specifically to Barcode, 2D and RFID and is prepared for any exchange of expertise and further contribution.

Chair TC and editing committee for the comments:
Heinrich Oehlmann

Consultation Topic No. 1
Characteristics and technical specifications of the unique identifier
Policy option no.1/1 versus no. ½

We favour option no. 1/1 for a "broad framework" for UIDs where running system would fit in without changes. Nevertheless UIDs shall conform to CEN, ISO or national standards for unique identification. Conforming to such standards would automatically include the features of a "harmonized" system as under "1.2" but would avoid detailed specification for the construct of serial numbers and its carrier by the regulator. Using compatible and interoperable standards automatically will achieve the required harmonization of unique identifiers.

Conclusion: The delegated acts should require a UID standard but should leave the details how to set up a unique identifier, specifically a serial number to the manufacturer or labeller selecting the appropriate standard. ISO/IEC 15418 supplies the means for unique identification constructs (see Annex 1),

Consultation item n°2
Manufacturer product code and pack number with or without country code
UDI constructs consisting of a unique company code, product number and serial number are very appropriate. Nevertheless a country code is not necessary to achieve it. Even the standard ISO/IEC 15459 Unique Identification sets the rules for identification without a country code where Issuing agencies supply uniqueness for company codes and concatenated information such as serial numbers. In addition to it there are some ISO conforming systems like HIBC which are more compact avoiding overhead by a one character system identifier. This enables global uniqueness just by unique company code and product related variables.

Conclusion: A country code is not necessary for unique UDIs and shall not be required as a mandatory information where any unique identifier constructs according to ISO/IEC 15418 with appropriate Application Identifiers, Data Identifiers and [1]System Identifiers (see examples under Annex 1).

Consultation item n°3
Additional product information Batch no, Expiry date included/not included in the serial number
Expiry date has a different function than the serial number and needed as single data field for control of the expiry. Therefore the Expiry date does not belong to a serial number.
Batch/Lot numbers might be incremented becoming a serial number or left as a separate field if the serial number can be unique for itself.
Conclusion: A serial number shall not include the Expiry date but may include a Batch/Lot number.

[1] See DIN 66401 System Identifiers and ISO/IEC 15418 part ANS MH 10. 8.2. Data Identifiers, Annex K) System Identifiers.

Consultation item n°4
National reimbursement number replaced by the abovementioned serialisation number or composed or used to build a serialized UID.

A) Replacement of a National Reimbursement Number - NRN would require change of national law, would require a change of country wide systems for manufacturer, wholesaler, pharmacies, hospitals and doctors and therefore cause an incredible amount of cost (should be investigated by parties with interest in such a change of whole systems) and efforts which is not necessary for the target to be achieved.

B) Composing a NTIN to another UID instead of replacement would cause even twice of the cost, because than the existing NTIN and the UDI applied to it would require systems to handle two numbers and to MAINTAINE two numbers,

C) Using a NRN for constructing a UDI would avoid the costs and efforts of A and B as the most efficient solution for the target. If a NTN of a specific country or system is not unique under the terms of CEN TC 225 Auto ID and ISO/IEC JTC 1/ SC 31 Auto ID, than CEN and ISO provide means how to add attributes to the NTIN to make it globally unique (example: National unique "PZN" becomes a globally unique "PPN", see www.ifa-coding-systems.de).

D)Unique ID systems where NTNs fit in are systems according to ISO/IEC 15459 Unique Identification where 33 Issuing agencies for unique company codes are available today and the Health Industry Barcode - HIBC and the Pharma Product Number as unique systems as well- PPN. Remark: The GS1 offers services as one of the 33 Issuing Agencies for Company IDs but the "GTIN" system restricts the adoption of NTNs for the reason of low capacity or license reasons. Using the GTIN would cause a dual numbering system in many cases in Europe as pointed out above under A and B.

Conclusion: Using a National Reimbursement Number (NTN) as data element of a UID is the most efficient way not only for European wide but also for worldwide unique identification and verification systems, the GS1 "GTIN" system product area does not perform for adopting NTNs globally. Therefore the construct under option 2 shall be avoided for establishing optimal systems in terms of efficiency.

Consultation item n° 5
technical characteristics of the carrier; linear, 2D-Barcode, RFID

Linear Barcode does have limited capacity specifically for UID and additional variables such as LOT and EXPIRY. 2D-Barcode, specifically ISO/IEC 16022 offers 10 times of capacity or a tenths of the space requirements than Barcode and includes error correction feature, linear Barcode does not have. Data Matrix is in use widely for medical devices already and partly for medicinal products as well. State of the art scanners read both linear and 2D-Barcode. In essence, 2D, specifically Data Matrix and ISO/IEC 18004 are in trend in industry healthcare and for applications in public areas (see QR As advertisement codes). 2D can be scanned even by Mobile Phones.
RFID can do more than Barcode and is attractive for specific solutions, specifically where Reading and writing is an advantage. This is not the case for medicinal products today. Just for carrying a UDI and product data RFID cannot compete with a optical code printed in high volume applications.

Conclusion: 2D-Barcode, specifically Data Matrix and QR Code perform perfect for UIDs applied in fast printing processes. RFID does not supply enough advantages today but may be for the future. So an Optical Readable Media (ORM) shall be required as one of the available ISO/IEC standards but 2D-Matrix shall be recommended as most efficient symbols.

Consultation Topic No. 2 Modalities for verifying the safety features

Consultation item n°6:
To verify the authenticity by access to a data base at the dispensing point.

Checking an incremented or randomized serial number is an appropriate method for confirming authenticity or not. Nevertheless, such an system does not exist yet for public access for good reasons of danger for attacks through internet access. Running systems with high volume of stored serial numbers are working in protected systems like the UID system of the Department of Defense of the US, the DoD. Learning from that experience the "End to End" concept was developed by the stakeholder of the manufacturers of medicinal products, wholesalers and pharmacists. The system allows access from authorized parties but not for the public and is protected against non-authorized loading of serial numbers as from access to it. Furthermore it does not require tracking and tracing data from and to next destination of the flow of goods and therefore an End to End system is easier to maintain, faster and cost efficient versus a centralized system collecting product information from any stage of a supply chain. End points are pharmacies and hospitals handing out medicines to patients. Other approaches may consider to route inquiries for information to manufactures may become an add on to End to End systems.
Exclusion: There are dispensing points for medicinal products to patients which do not belong to a regular supply chain like surgical departments, ambulances and dentists. They do not dispense medicines. Nevertheless they should be allowed to use a verification system as an option.

Conclusion: The End to End Verification system is the today's most efficient and most secure system and performs for the first choice of different concepts. Surgical entities such as Dentists shall be enabled to use a verification system but excluded from mandatory use.

Consultation item n°7: Additional random verifications at the level of wholesale distributors.
In case of End to End Verification there is no urgent need for mandatory scanning at the points of a supply chain where the wholesaler has its place. Nevertheless enabled access to the parties involved would be an advantage in case of doubts or other reasons.

Consultation Topic No. 3 Provisions for the establishment and accessibility of the repository system)

Consultation item n°8: Stakeholder governance, EU governance or National governance for a repositories system
Stakeholder governance would be attractive for all three parties, because if stakeholders take care for the repository system, than it promises most support by the stakeholders and it would discharge EU and national bodies.

Consultation item n°9: Information of a commercially sensitive nature
Information that allows the number of packs manufactured, the point of dispensation of a pack, the point of re-packaging of a pack are not part of a verification system and belongs to sensitive information and shall be avoided for general access. Just a UID shall be the key for authenticity check without sensible information.

Consultation item n°10:
To 4.2. Protection of personal data: Agreed with 4.2.
To 4.3. Re-packaging of medicinal products: Agreed with 4.3

CONSULTATION TOPIC No. 4

Consultation item n°11 and n°12: LISTS CONTAINING THE MEDICINAL PRODUCTS OR PRODUCT CATEGORIES
We would like leave the answers to associations for pharmacists.

E. CONSULTATION TOPIC Nr. 5 - OTHER ISSUES
We don't have a specific comment for the moment for consultation topic E.

Appendix 1
Unique Identifier constructs.

A Unique Identifier shall be a generic construct where standardized constructs and data elements fit in such as:

		UID construct				
***System ▼**	**System Identifier**	**AIs/DIs**	**Company ID**	**Product no**	**SN**	**Add. Data**
ASC	Macro 06	X	X	X	X	X
EUROCODE	!	(X)	X	X	X	X
GS1	FNC1	X	X	X	X	X
HIBC	+	X	X	X	X	X
PPN	Macro06	X	-	X (registered)	X	X

**Systems conforming to ISO/IEC 15418*

The examples above qualify to be a Unique Identification Systems by unique identifiers.

Comments provided by: Joined Technical Committee of EHIBCC