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> Sendung 2 Seite(n) Versandart per E-Mail Anlage(n) 8 Seite(n)

Kopie an

Ihre Kundennummer

Ref: European Commission`s consultation paper on Delegated Act for a Unique Identifier etc. from Nov. 18, 2011

Dear Sirs,

We submit herewith our comments to the consultation paper on Delegated Act for a Unique Identifier etc. from Nov. 18, 2011 as attachment "IFA Comments".

As an introduction we will give you some background of our organisation, our role within the German healthcare sector and the coding specifications which we provide for the German market.

IFA (Informationsstelle für Arzneispezialitäten GmbH) is the information and registration organisation responsible for the German Pharmaceutical Central Numbering system "Pharmazentralnummer (PZN)". We are located in Frankfurt/Main and were founded in 1987 by the associations ABDA, BPI and PHAGRO (please refer to list of stakeholders on page 2) in order to issue and register the reference numbers (PZN) for pharmaceutical companies and their products.

A primary function of the PZN is it's use in the billing of prescriptions for the state health insurance fund. This assignment is on behalf of the German legislator. Additionally the PZN is used to support all market actors with the relevant pharmaceutical and economic data for these products.

The IFA database currently covers approximately 400,000 pharmacy-customary products. Each year more than 3,500 manufacturers worldwide apply for assignment of PZN for approximately 50.000 products. The PZN database contains up to 80 fields for legal and logistical purposes. This database is continuously updated by IFA and with participant actors being informed with a biweekly information service

The PZN is currently encoded in Code 39 the specification of which is maintained and supported by IFA. In order to address future requirement, the German pharmaceutical companies, wholesalers and retailers have decided to enhance the pharmaceutical-numbering system (PZN). For this purpose, the IFA, as Issuing Agency, has created a coding system which allows the PZN to be converted into a unique international product number and combine this with further information encoded in a Data Matrix Code.

The scope of the new numbering system has been designed to provide global cover and to use AIDC technologies which are in full accordance with ISO & IEC standards. The nomenclature thus created for the porting of national number systems to globally unique identifiers is completely suitable for representing all existing number systems in a consistent, mutually exclusive form.

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We explain the details in the document "IFA Comments, on pages 7 and 8.

One of the primary benefits of this system for harmonisation is, that there is no change of existing product codes and it is offered by the IFA free of any licensing fees. The IFA is also prepared to consider the transfer of the assignment and maintenance of the "Pharma Prefix" (PRA-Code).

The stakeholders of the German pharmaceutical market, namely the associations listed below mandated IFA to submit these comments to you:

ABDA - Bundesvereinigung Deutscher Apothekerverbände (German Federal Association of Pharmacists)

Bundesverband der Arzneimittel-Hersteller e.V. (BAH) (German Medicines Manufacturers` Association)

Bundesverband der Pharmazeutischen Industrie e.V. (BPI) (German Pharmaceutical Industry Association)
Bundesverband des Pharmazeutischen Großhandels – PHAGRO - e.V. (Association of Pharmaceutical Wholesalers)

Pro Generika e.V.

(Association of Generic Medical Manufacturers)

Verband Forschender Arzneimittelhersteller e.V. – vfa (Association of Research-Based Pharmaceutical Companies)

Further information concerning our organisation and the Coding System can be found under the following link: www.ifa-coding-system.org

Please address any questions related to our comments to:

Klaus Appel, Managing Director.

Kind regards

Encl: Comments on Consultation Paper; Filename: "IFA Comments"