

# Healthcare Case Study

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## ***A Live Example from Germany Significant Cost - saving through EDI Hospitals Save Up to 45%!***

The *Hochtaunus-Kliniken gGmbH* and the *Kreiskrankenhaus Dormagen* both opted for the classic EDI procedure based on the EAN.UCC System. This was realised successfully, as proven by the cost-benefit analysis.

As first pilot hospital of CCG (EAN Germany), the *Hochtaunus-Kliniken* implemented integrated electronic processes beginning with Orders, continuing with Despatch Advice and concluding with Invoice. The *Kreiskrankenhaus Dormagen*, likewise implemented EDI in this manner. CCG (EAN Germany) aims to implement EDI in pilot hospitals, based on the communication standard EANCOM<sup>®</sup>. Processes are documented in a before/after comparison, and each involved hospital conducts a cost-benefit analysis.

This analysis is based on a before/after comparison of the processing of article master data, orders, goods received and invoices. The real effort to conduct this study consisted of recording the time necessary to complete individual processes. The measured processing time was then multiplied by the average in-house personnel costs.

### **Result of *Hochtaunus-Kliniken gGmbH***

Taking into account the necessary EDI capital investment, savings of 28% in the first year and 41% in each of the following years are achieved – capital investment already being amortised in the first year.

<b>Process</b>	<b>Savings Euro p.a.</b>	<b>Savings % p.a.</b>
Acquisition of articles	430.54 €	34 %
Changing article master data	267.60 €	57 %
Order	831.95 €	25 %
Deliveries	3,698.88 €	57 %
Invoices	1,597.46 €	46 %
<b>Total</b>	<b>6,292.79 €</b>	<b>41 %</b>

### **Result of the *Kreiskrankenhaus Dormagen***

Taking into account the necessary EDI capital investment, savings of 43% in the first year and 45% in each of the following years are achieved – capital investment already being amortised in the first year.

<b>Process</b>	<b>Savings Euro p.a.</b>	<b>Savings % p.a.</b>
Acquisition of articles	1,050.33 €	48 %
Changing article master data	7,369.42 €	63 %
Order	1.676.44 €	8 %
Deliveries	6,695.30 €	36 %
Invoices	17,519.48 €	81 %
<b>Total</b>	<b>33,836.98 €</b>	<b>45 %</b>

### **Project assumptions**

As the means to realise their EDI projects, the pilot partners quickly came to an agreement in favour of the EAN.UCC System, the latter being the only adequate enabling technology to meet all the needs of efficient electronic communication:

- GLN: Global Location Number, for the worldwide unique identification of the pilot partners (i.e., sender and recipient of electronic data deliveries)
- GTIN: Global Trade Item Number, for the worldwide unique identification of products
- EANCOM<sup>®</sup>: international EDI Standard as the format for data deliveries for the messages Order, Despatch Advice and Invoice

The EAN.UCC System can be used irrespective of the IT infrastructure employed for communication purposes - either for bilateral communication between industry and hospitals or for communication with or via marketplaces. Especially in this aspect, the unambiguousness of the GLN and GTIN, as well as the design format of EANCOM<sup>®</sup>, plays a decisive role in avoiding different solutions in data communication. The end result saves costs instead of producing additional work.

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## ***Australia's Central Medicines Repository*** ***- A Critical Piece of Public Health Infrastructure***

### **Purpose**

Access to a trusted, authenticated, central source of medical product information will ensure that the many electronic health systems being used by doctors, pharmacists and hospitals are referring to the same medicine and the information on that medicine is consistent across the various systems.

The repository provides the opportunity to:

- enhance the quality use of medicines;
- improve clinical outcomes;
- provide continuity of patient care; and
- reduce the risk of medication error.

The central medicines repository is a critical piece of public health infrastructure.

The repository will enable the reliable transmission of medicines information between health care providers. Each medicine will be uniquely identified using the EAN.UCC systems' Global Trade Item Number (GTIN), which will ensure that the many health systems being used by doctors, pharmacists and hospitals refer to the same medicine.

Establishing the repository will be an important step towards achieving better health outcomes for Australians. Access to a trusted central source will help to reduce adverse events associated with the use of medicines, which can occur, for example, when different medicines have similar-sounding names. It will improve the accuracy of medicines information communicated between the various systems now used and will help to achieve quality use of medicines for all consumers.

Improving the reliability of the electronic transmission of medicines information in both the hospital and community health settings could save lives and reduce hospitalisations.

Population of the repository with all Australian pharmaceutical and complementary medicines is expected to be a long-term project. There are five key stages required to achieve this:

1. system development;
2. initial population;
3. availability to data recipients;
4. review process; and
5. ongoing update.

### **Background**

#### **1. Medicines Coding Council of Australia**

In November 1999, the Australian Government Department of Health and Ageing, HIC (prev. Health Insurance Commission) and Standards Australia sponsored a national forum on a Pharmaceutical Terminology for Electronic Data Exchange. The forum established the Medicines Coding Council of Australia (MCCA) to further action their objectives. The MCCA consisted of a voluntary membership of interested people representing all sectors of healthcare including suppliers, wholesalers, medical clinicians, community and hospital pharmacists, software vendors, database distributors, drug usage researchers and

government. EAN Australia was an active participant in the MCCA's meetings. MCCA's work culminated in November 2002 with the completion of a minimum dataset to define the core data items of a central medicines data repository and a consultancy, which developed a strategy for the implementation of the repository.

## **2. EANnet Pilot project**

Following a request from the MCCA, a pilot project was conducted from March to November 2001 to:

- verify previously collated data for each supplier and provide GTIN codes to additional products where they existed; and
- demonstrate the process controls and functionality of the EAN Australia electronic data catalogue and synchronisation tool, EANnet.

The findings from the pilot have been documented in the Pharmaceutical Coding Pilot Outcomes report released in April 2002<sup>1</sup>.

## **3. Consultancy**

The Department commissioned an independent consultancy to address, on behalf of the MCCA, issues concerning the organisational form and legal structure of MCCA, governance, business model and liability, and the role of the Australian Government in the MCCA.

The consultants reported<sup>2</sup> that there is widespread industry support for a central medicines data repository. The MCCA EANnet pilot<sup>3</sup>, which was jointly conducted by the Department of Health and Ageing and EAN Australia, indicated that the effort and cost for suppliers in participating in the establishment of the repository and its maintenance would be minimal.

The key recommendations of the report were that the Australian Government take responsibility for the establishment and management of a central medicines data repository and that the repository be hosted by EAN Australia.

## **4. Australian Government Approval**

In May 2003<sup>4</sup>, the Australian Minister for Health and Ageing announced the Australian Government's approval of funding to support this initiative. This funding includes the project costs of developing the repository, quality assurance processes, project management, consultancies, communications materials, and phone and direct contact support for suppliers and software vendors.

### **Hosting of Central Medicines Repository by EAN Australia**

The central medicines data repository will be hosted by EAN Australia Limited. EAN Australia is a non-profit standards organisation that locally administers the global multi-industry system of identification and communication for products, services, assets and locations—the EAN•UCC system. It currently operates a well-established data catalogue and online data synchronisation service in Australia known as EANnet.

The existing EANnet system is being modified to cater for medicines data and the associated extra functionality.

EAN Australia provides a system that has:

- an Internet interface;
- existing infrastructure that provides platform stability;

<sup>1</sup> MCCA – Pharmaceutical Coding Pilot – Outcomes Document 9 April 2002 - <http://www.medicconnect.gov.au/pdf/pilotoutcomes.pdf>

<sup>2</sup> Walter & Turnbull – Department of Health and Ageing – Implementation of a Central Medicines Data Repository (Nov 2002) <http://www.medicconnect.gov.au/pdf/wtfr2211.pdf>

<sup>3</sup> see footnote 1 above

<sup>4</sup> Media Release –Minister for Health and Ageing - Medicines Database to Provide Better Health Outcomes – 19 May 2003 - <http://www.medicconnect.gov.au/pdf/cmr.pdf>

- proven delivery reliability;
- high quality system maintenance and support;
- existing security measures, reviews and system auditing; and
- an established user registration system.

#### **System features – Central Medicines Repository & EANnet**

The proposed medicines repository system, which will be hosted within the EANnet system, incorporates a workflow application to facilitate the:

- data entry and updating of product information by suppliers;
- submission of product information to a quality assurance process for review;
- stringent quality assurance process to be conducted on all product information including the allocation of products to therapeutic groups; and
- suppliers' role of performing a final review and release of their product information for public access.

All changes made to product information will be captured within an audit log with details of 'who, when and what'. This will provide a complete audit history for any medicine in the repository.

Searching and reporting facilities will be available across the repository. It will also provide a structured and controlled process for the download of product information to software vendors and other data recipients<sup>5</sup>.

#### **Products**

The aim is for the repository to eventually hold information on the following products that are currently available on the Australian market:

- all Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) items, including listed dressings and some therapeutic devices such as blood glucose diagnostics and lubricant eye drops;
- other prescription medicines;
- over-the-counter (OTC) medicines; and
- complementary medicines.

Suppliers having a large number of products are asked to give priority to 'commonly prescribed medicines' when adding to the repository as part of the initial population. Suppliers are encouraged to add other products as well, if possible.

The product information required for the repository is limited to the details that are currently publicly available on the product package including active ingredients, dosage form, strength, AUST R/AUST L number (Australian Therapeutic Goods Register number), schedule, container, and number of items.

#### **Benefits for suppliers**

An established central source is expected to significantly reduce the time and effort required by suppliers in providing current and accurate product information to software vendors, database distributors and trading partners.

The additional EANnet services of full data synchronisation are also available to suppliers. Data synchronisation supports more efficient e-commerce supply chain management practices with a range of direct and indirect benefits to industry.

<sup>5</sup> Refer <http://www.medicconnect.gov.au/technical/coding/recipients.htm> for more information.

As it will take some time for all trading partners to adapt their current systems to participate in data synchronisation, not all benefits will be realised in the short term.

**Implementation Timeframe**

Population of the repository with all Australian medicines is expected to be a long-term project.

There are five key stages<sup>6</sup> required to achieve this:

1. System development;
2. Initial population;
3. Availability to data recipients;
4. Review process; and
5. Ongoing update.

The system development stage, incorporating enhancements to EANnet, commenced in January 2004, and the final development of the project is expected to be completed in the first quarter of 2005.

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<sup>6</sup> Refer <http://www.medicconnect.gov.au/technical/coding/timeframe.htm> for more information.

## ***Logistical Processes are Closely Connected with Healthcare Process Case Study from the Netherlands***

Nearly every day, companies everywhere start using the EAN.UCC System. The reasons differ for each company. Market developments, new collaborations and logistical changes are all reasons to provide articles with a Global Trade Item Number (GTIN). Magnafarma is one such company that seized on both the developments in its own organisation and sector-specific developments as the catalyst for the implementation of the EAN standards. We met Andries van Duijvenbode, head of the administrative office at Magnafarma, to discuss these developments.

Magnafarma got off to a quick start in allocating GTINs to its products and even in applying EAN.UCC symbols to products. What was the reason for using EAN coding right away?

“Around the middle of July 2000, a number of initiatives were started up with the objective of arriving at a new standard for article coding in the pharmaceutical industry. Early in 2001 the Federation for the Dutch Generic Pharmaceutical Industry (Bogin) became involved whilst, at the same time, the Platform for Logistics of Care Products (PLZ) took on a coordinating task. The main objective was to achieve efficiency improvements in the logistical and administrative processes surrounding care products. It was found that the EAN.UCC System is the most suitable standard to achieve this.”

“In order to achieve the objective, the GTIN first had to be introduced for primary article identification in the logistical processes. One condition for this was the GTIN being linked to the existing ZI number (identification in national Database; Z-Index). It is only by doing things this way that the logistical processes are fully integrated with the care processes.”

“Wholesale company Brocacef was also involved in the process right from the start. As a production company for the Brocacef holding, Magnafarma was prepared to run a pilot. This way, the various disciplines in this business sector were able to gain experience with EAN standards. This pilot virtually coincided with the implementation of the new layout and the improved colour coding on the generic Genfarma label medications. This made the introduction of the EAN bar code and the actual printing of the bar code on the packaging relatively simple.”

What are your experiences with the introduction of the EAN.UCC system?

“After more than eighteen months nearly all primary packaging has been printed with an EAN bar code. Within Magnafarma and also for Brocacef, the wholesaler, the introduction of the article code has been virtually problem-free. The ERP systems that were used were able to read both the existing HIBC code and the EAN bar code. Within the system a link was established between both numbers. This meant that processing throughout the entire procedure presented no problems.”

“The packaging development department forwarded specifications to the suppliers and printers of the packaging materials to ensure we had guarantees on the readability of codes on the various types of packaging. In order to maintain coordination in the entire chain we decided to include the ZI number on the primary packaging as well, although no longer as a bar code.”

“The requirement for this - temporary - measure is the logical result of a pilot. It is not possible to immediately change the entire chain over to the new system. Furthermore, not all data systems are able to process two different codes. Neither was there a central databank that could record the link between the ZI number and the various GTINs.”

“Thanks to the broad platform on which the entire chain is represented, such obstacles are adequately handled and resolved in a constructive manner. For instance, there is now a central databank like the existing EAN DAS, in which the logistical information for care



products can be found. In addition, there are a number of software producers that have adapted their systems, while others are engaged in consultations to ensure these kinds of procedures are steered in the right direction. These experiences and the structured consultation between the parties have resulted in the decision to provide the Single Unit Dose packages produced by Magnafarma with a GTIN as well.

What is your advice to fellow companies within the healthcare sector?

“In view of the above, there is no question for us as to whether this initiative should be continued on a broader scale. Magnafarma pleads the case for a rapid further introduction of the EAN system in the entire care chain. The advantages of management within the logistics of the care sector, as they have long been known in, for instance, the food sector, are indisputable. Especially now that cost management in the healthcare sector is a hot topic, the full implementation of the EAN system can be an excellent aid.”

“Where, until now, we have talked about GTINs on primary packaging, Magnafarma now also applies the GTIN as a logistical information carrier on outside packaging and pallets. Combined with, for instance, Radio Frequency scanning, this can achieve further efficiency benefits.”

Finally, a comment that stems from everyday practice. “Labelling care products with a ‘proprietary’ (bar)code system upon receipt is a thing of the past after the implementation of the EAN system. After all, the link between care information and logistical information is now organised from one central point.”

Magnafarma, located in Zaandam, The Netherlands, produces a high-quality and extremely broad range of medications for pharmacists and GP’s with their own pharmacy.

This product range includes the generic range of medications produced under the Genfarma label. Magnafarma also provides the market with parallel imported speciality medications that are repackaged in-house. Specific eye preparations are developed and registered under the HPS label.

The company’s annual production exceeds one billion tablets, coated tablets and capsules packaged in jars or strips, and hundreds of tonnes of syrups (and other liquids), ointments and creams, packaged in bottles, pots and tubes. This makes Magnafarma one of the largest pharmaceutical production companies in the Netherlands.

Magnafarma was the first producer to use the so-called ATC colour coding on the Genfarma packaging. This colour coding contributes to patient and pharmacists-friendly packaging that is also printed with, among other things, colour codes for strength indication and bar coding.

Magnafarma also supports a large number of pharmaceutical companies in their clinical trials. For this purpose the company supplies the medications in question as well as identical-looking placebos in the required packaging and administering method.

#### Bedside scanning prevents medication errors

The American healthcare sector is focusing on minimising errors in administering medication. By scanning medication at the patient’s bedside, errors can be reduced by as much as 50% or more, according to the Federal Drug Administration. In the Netherlands, too, so-called bedside scanning is the very latest development. The new EAN bar code, Reduced Space Symbology/Composite Symbology, plays an important role in this development. We visited the TweeStedenziekenhuis (*TwoCity Hospital*) in Tilburg, The Netherlands.

It is early in the morning and the physician is doing his rounds. At a patient’s bedside the physician dictates a prescription to his assistant. The assistant writes the prescription on the patient’s chart by hand. The prescriptions are collected and entered into the hospital

pharmacy database. After this a printed version of the prescriptions is returned to the ward, where the prescription is added to the patient's chart. The medication is then distributed in the wards based on the distribution list. When the nurse does her rounds she checks the prescription on the patient's chart and administers the medication. It is easy to imagine all the things that can go wrong in this process. This was the reason for the TweeStedenziekenhuis in Tilburg to optimise this process.

#### In-house labelling of medications

Bertil Lenderink, Chief Hospital Pharmacist in the ZiekenhuisApotheek Midden-Brabant (ZAMB) (*Hospital Pharmacy of Central Brabant*): "We have been labelling our medications in-house ever since the Seventies. This way, each unit dose (such as an ampoule or a pill) is identifiable. In the past the label from the medication that was administered would be stuck onto the patient's chart, next to the physician's prescription. This way we were working on building in extra control moments, even then. We have not rested on our laurels since those days. The introduction of PDAs (Personal Digital Assistants) and advanced software programmes have brought the optimisation of the medication process a lot closer." In this project, Theriak is providing the software and Zetes is providing the hardware.

#### Electronic prescription and registration

In this context, the TweeStedenziekenhuis commenced a project last year. The main objective was reducing the number of stages between prescribing and administering medication. In addition, manual actions had to be replaced, as much as possible, by an automated system. The result is a system that allows electronic prescription and also electronically registers administering of medication. Lenderink: "The system ensures that every action is traceable, which reduces the chances of errors. The physician enters the prescription on the PDA. The distribution list is printed in the pharmacy and the medication is distributed to the wards. In the ward the medication is now set out by patient. During the distribution round the nurse scans the patient and the medication and the system indicates whether this medication must indeed be administered at that time. This means that every step in the process can be traced. If the nurse scans medication that should not be administered at 10.00 am but rather at 02.00 pm, this will be registered." A guarantee, therefore, that the right medication is administered at the right time!

#### Labelling medication

Even today, labelling of medication is still partly done manually by hospital pharmacy staff. Bertil Lenderink: "You can well imagine how much time and money is involved in this process. Every ampoule is removed from its packaging and given a label so that it can be identified. We would of course prefer to receive medication from the manufacturer or packaging company already equipped with a bar code. EAN.UCC offers a solution to this situation in the form of Reduced Space Symbology/ Composite Symbology (RSS/CS)."

#### On the way to medication coding

RSS is a small linear symbol that has been specifically developed for products that are so small they cannot be provided with a traditional EAN.UCC symbol, such as ampoules or hypodermic needles. In addition, an additional symbol can be added: CS, in which extra information can be incorporated. It is clear that RSS/CS offers a solution for small products, as a number of international pharmaceutical companies, such as Abbott and Pfizer, apply the bar code. Bertil Lenderink: "ZAMB is now ready to start using RSS/CS. Tjoapack, a medication packaging contractor for the pharmaceutical market, is assisting us in this process." Eric Tjoa, managing director and proprietor of Tjoapack: "As early as 1989 we were the first company in the Dutch market to supply unit dose packages with bar codes. We have been closely involved in the development of standardised unit dose packaging for Dutch hospitals."

#### Optimised medication monitoring

It is therefore not surprising that Tjoapack is the first company able to print the EAN.UCC RSS/CS. "Tjoapack uses in-line printing techniques (printing the foil during the packaging

process). This means we can print labels and blister packs quickly, cheaply and in a flexible manner. By using EAN, ZAMB chooses a world standard that I anticipate may well become the system that is used exclusively. The system also makes it possible to reuse medication returned by wards. Research by the Dutch Association of Hospital Pharmacists (NVZA) indicates that waste of medication can be reduced from 12.4 percent per year to as little as 2.5 percent. But the most important thing is the fact that patients can be certain that they will receive the right medication in the right quantity and at the right time!" says Eric Tjoa.

#### Statistics about errors in administering medication

The fact that medical errors can have fatal results was demonstrated, among other things, by the controversial report entitled 'To Err is Human', published in 2000 by the American Institute of Medicine. In 1993, (human) error in the administration of medication, such as administering a wrong dose or the wrong medication, caused the death of 7,000 people in the United States alone. So far there is no reason to assume this situation is any different in the Netherlands. This means we are talking about 150 to 300 deaths per year in our country.

#### The answer: bar codes on medication

The Food and Drug Administration (FDA) aims to have every item of medication in the US packaged and bar coded separately. According to the FDA, bedside scanning can reduce the number of (human) errors by over 50%. In the Netherlands at least six different coding systems are used at this time. Research carried out by the Federation of Wholesalers (BG Pharma), showed that the EAN.UCC System was the only bar code system to meet all criteria. In order to stimulate a change to the use of EAN coding for pharmaceuticals, the UAC Pharma Foundation and the Platform for Logistics of Care Products were established in 2000. Following these initiatives, the Dutch Association of Hospital Pharmacists (NVZA) decided to apply the EAN Reduced Space Symbology/Composite symbology (RSS/CS) to all unit dose medications.

#### Further information

For further information about RSS/CS please contact EAN Nederland. The Customer Service telephone number is +31 (0)20 511 38 88, or contact consultant Sarina Pielaat on +31 (0)20 511 38 20 or by e-mail: [spielaat@ean.nl](mailto:spielaat@ean.nl). For further information about general developments in the healthcare sector Marcel van Trier, EAN Nederland sector coordinator, can be contacted on the same telephone number or via e-mail: [vantrier@ean.nl](mailto:vantrier@ean.nl).

## **A pilot project conducted at Santa Catarina Hospital, Brazil - EAN.UCC System streamlining the hospital supply chain**

There was a lack of unified barcodes on products and that was a critical problem for the automation of internal operations. This situation throughout Brazil was considered a source of inefficiency since it requires product re-labelling, meaning re-work and undesirable additional material handling. The Hospital Working Group, representing the most important Brazilian healthcare companies, includes hospitals, manufacturers, suppliers and solution providers, set out to solve this unsatisfactory situation.

Several barcode options to encode product identification, lot number and expiry date data were studied by the working group. A standardised solution, based on RSS and Composite Symbologies, was defined to facilitate its adoption by manufacturers and to guide the development of hospitals internal systems. In addition, an implementation guideline<sup>(1)</sup> and an animated video<sup>(2)</sup> were prepared to help its adoption and promotion.

A pilot project was conducted at Santa Catarina Hospital, located in São Paulo city, as a starting point for the adoption of this solution by the Brazilian healthcare sector.

The 97- year- old 43,000 (m<sup>2</sup>) Hospital operates with 1,050 staff, 235 beds, a surgical centre with 14 operating theatres and an obstetric centre with 5 operating theatres, as well as 50 ICU beds, performing around 1,400 surgical operations and performing over 300 births every month. The Hospital is supplied by over two thousand registered suppliers that replenish the six different thirteen thousand item capacity stock holding areas.

Within this environment, an information management system was absolutely necessary to assure operational efficiency, costs and stocks reduction, patient safety, and data management. An automated data capture system, considered critical, was established with the EAN.UCC System at the heart of the solution.

Every single item consumed in the hospital is now marked with an EAN.UCC bar code enabling the identification code of all products to be electronically captured from products as they are received and administered to patients. For drug dispensing operations, a PDA (Personal Digital Assistant) with scanner has been adopted. The prescription comes in directly to the PDA screen. Requests arrive every two hours and the products are delivered one hour later. Apart from the gains in cost and time, considerable improvement in the relationships between the nursing and the pharmacy teams was achieved.

The EAN.UCC System helped to enhance safety at Santa Catarina, an indispensable factor in the successful operation of a hospital. Furthermore, the hospital achieved significant cost reduction and efficiency within its supply chain. EAN.UCC System brings greater speed and reliability to a process that was already very advanced. It shows that bar coding and automation have a great deal to contribute to both controlling and improving processes.

"Coding Guide for Medications and Health Products" –

[http://www.eanbrasil.org.br/servlet/ServletContent?requestId=16&lang=en\\_US](http://www.eanbrasil.org.br/servlet/ServletContent?requestId=16&lang=en_US), click on "virtual library", then "menu", then click on "Guide" to choose the document.

"Hospital Chain Management" – [http://www.eanbrasil.org.br/servlet/ServletContent?requestId=16&lang=en\\_US](http://www.eanbrasil.org.br/servlet/ServletContent?requestId=16&lang=en_US)

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## ***Traceability and Efficiency of the Processes that Assure Drug Safety***

### ***Case Study from Brazil***

#### 1. Rationale

One of the most outstanding trends in the Brazilian pharmaceutical product market is the use of logistic operators for storing and distributing medications. Both for the industry and the logistic operators, the increase in efficiency and cost reduction have become primordial factors for the health of their business.

Another important factor is that the Brazilian market increasingly seeks to establish measures to avoid the occurrence of drug frauds and cargo deviations. This is one of the main concerns of ANVISA (“Agência Nacional de Vigilância Sanitária” – Brazilian Sanitary Surveillance Agency), the government’s main regulating agency for the pharmaceutical sector, which has established regulations to guarantee drug safety and employing the traceability of all drugs sold in the country as a resource.

Furthermore, in order to attain these objectives, automation of processes is an essential tool.

#### 2. Key Players

The Brazilian Pharmaceutical Industry;  
Logistic Operators;  
Pharmaceutical Distributors;  
Large Pharmacy and Drug Store Chains;  
ANVISA (“Agência Nacional de Vigilância Sanitária” – Brazilian Sanitary Surveillance Agency);  
Industry Associations;  
EAN BRASIL

#### 3. Current vs. Previous Business Processes

About 10 years ago, the pharmaceutical industry was the only one responsible for the storage of its products and their distribution to customers, that is to say, each company maintained its own specialised structure for performing these activities.

Evidently, as the pharmaceutical industry’s core business is not the storage and distribution of medications, much more attention was paid to the purchase, production and sales of medications than to their physical distribution. It was frequently set aside as something of little importance.

As a result the companies operated with high rates of inefficiency, had difficulty in optimising the distribution process due to the diversity of customers and locations and by the consequent lack of scale created by this scenario, the consolidation of cargoes practically did not exist and operating costs were high.

Pharmaceutical laboratories realised that these operations caused a significant impact on their profits. Thus, another business model began to be established, in which these activities would be performed by logistic operators.

From a simplified viewpoint, logistic operators started to manage all the logistics of medication distribution. From their customers – the pharmaceutical laboratories – they receive their entire production, store, control stocks and ship the products to the companies’ customers. After information held on drugs is scanned from bar code labels and registered, they are distributed to the 27 Brazilian states.

With the development of an automation project for managing the movement of products from receipt through to dispatch, the Distribution Centres automated their operating processes through a completely computerised system, which uses the UCC/EAN-128 standard bar code for identifying products and logistic units, optical scanners and mobile computers, which makes the separation and dispatch of products easier.

Scanning of labels with UCC/EAN-128 standards containing data on GTIN, expiry date, lot number and quantity of items, updates the system with this data at the exact moment that the products cross the company's receiving docks.

The standardisation of labels allowed the implementation of automatic systems for picking and sorting the logistic units, which controls the logistics of medication storage and distribution, increasing the safety margin throughout the entire process even further.

Several advantages obtained from contracting these operators have been proved: greater flexibility in administering the processes, specialised services with diversification at the various stages of the Supply Chain, increase in operating efficiency, stricter control of the Supply Chain.

The challenge in this scenario is the integration of logistic operators' systems and processes with those of the pharmaceutical laboratories.



Ricardo Gamarski – Consultant of ANVISA (“Agência Nacional de Vigilância Sanitária” – Brazilian Sanitary Surveillance Agency);

“Given the immense number of products that need to be controlled, ANVISA has made a straightforward option of using technology intensively for the management of all information. The EAN•UCC bar code is the basis of this strategy. (...) “The central objective is that ANVISA obtains the data in order to be able to trace the products, starting from manufacture right through to the consumer, inside and outside the country. Therefore, we think the EAN•UCC standard is one of the best ways”.

#### 4. EAN Standards and Technology Used

EAN BRASIL has advised the business community on the development and application of standards that make it possible to assure drug traceability as well as to improve the services and processes of the entire pharmaceutical chain. The traceability model drawn up on the basis of the EAN.UCC System standards, involving the identification of trade items, logistic units and messages for electronic data interchange, allows additional data to be coded (expiry date, lot number, quantity of items and others), which is basic information necessary to assure the traceability of products and logistic units.

The Healthcare Working Group, coordinated by EAN BRASIL and composed of professionals from the areas of supplies, information technology and administration of major Brazilian hospitals, as well as representatives of the Pharmaceutical industry, has been discussing the sector's challenges and developing tools to improve the services provided. As one of the results of this work, EAN BRASIL has made available the [Medicines and Medical Products Codification Guide](#), which recommends the data structures and bar codes to be applied to products destined for hospitals starting with logistic units and going through to unit doses. In addition to this Guide, the animated video [Hospital Chain Management](#) shows the main operations involved in the process of buying and dispensing drugs and healthcare products in

the hospital environment. Demonstrations are given of the EAN.UCC System bar code applications for identifying unit doses, logistic units, patients and professionals, as well as EDI messages employed in the integration between the hospital and its suppliers and customers. The above is another important matter that has been discussed based on the EANCOM standards of the EAN.UCC System.

EAN BRASIL has also provided ANVISA – “Agência Nacional de Vigilância Sanitária” (Brazilian Sanitary Surveillance Agency) – with technical advice on questions related to drug safety. The EAN.UCC System standards have been studied by the agency as a suitable resource for assuring the control and traceability of all medication sold in the country.

The UCC/EAN-128 symbology has been adopted by pharmaceutical laboratories for identifying their logistic units (boxes and pallets), as it allows logistic operators to capture and process coded data rapidly. Among the main coded data are the GTIN, expiry date and lot number. This has made the use of automatic sorters to speed up the process of separating goods even further.

## 5. Value Proposition

The main benefit obtained is complete control of the stages in the Supply Chain, providing fundamental tools for risk analysis and management. With better control of risks, pharmaceutical companies and logistic operators are able to maximise their profits, as well as offering their customers and consumers greater safety and reliability.

The risks of financial losses and harm to the company’s image and public health in the cases of recall are significantly reduced, as the process control information, starting with production and going through to distribution, is stored and easily recovered through the records kept as a result of bar code numbering, which speeds up and makes decision making easier.

Better stock management, greater efficiency in relationships with customers (through the logistic operators) and more adequate planning of market requirements mean gains in competitiveness and optimisation of processes.

Another important benefit is the factor known as product differentiation. By obtaining reliability and safety in processes and products, the company is able to differentiate and add value to its products.

The customers (shippers) are able to follow-up on line the movement status of each product.



Dr. Lauro Moretto – Director of Febrapharma (“Federação Brasileira da Indústria Farmacêutica” – Federation of Brazilian Pharmaceutical Industry)

EAN Brasil was the entity responsible for providing the country with an extremely important methodology for automating the sale and product identification processes in retail, in distribution and in transport, by the use of the EAN-13 and UCC/EAN-128 codes.”



Dr. Pedro Zidoi – President of ABCFarma – (“Associação Brasileira do Comércio Farmacêutico” - Association of Brazilian Pharmaceutical Retailers)

By using the automation tools, like bar codes and EDI, the industry brings the added-value to the characteristics of the product. For distributors, this Technology makes the logistic operations of products more efficient and quicker. In retailing, automation represents security for more efficient administrative stock management”.

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