UNDERPINNING PATIENT SAFETY

Recommendations and Guidelines for product coding within the UK Pharmaceutical Supply Chain

Developed by the Pharmaceutical industry and profession in the UK.

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1 Executive Summary

The ability to deliver the benefits highlighted in this report and save patient lives will not be feasible without the total commitment of the industry and the government in mandating these proposals. If this is not embraced, there is a high risk that other fragmented and less effective, solutions will be imposed. The need for change is now.

This report, compiled by a cross-industry working group, strongly recommends:

1. That the EAN.UCC open global standards (of product identification and RFID (EPC)) is formally selected for the coding and symbolisation for all pharmaceutical products available in the end to end (active ingredient to consumption) UK supply chain;

2. That a review of the general processes and practices related to scanning, re-labelling and repackaging (loss of original product ID), dispensing and supply chain traceability is quickly undertaken and that the output from this review should address patient safety issues;

3. That a Joined-up Work Programme consisting of industry, profession and government stakeholders is established immediately to evaluate and recommend as appropriate the introduction of coding and symbolisation at all relevant levels of product packaging and processes to enable full end to end traceability, accounting for the emergence of new technologies such as RFID/EPC, defining where required migration paths to protect stakeholders' investment.

The recommendations of this report take into consideration the need to build a sustainable, scalable future proof solution that can be adopted by the broad sector where through a formalised approach can derive benefits now from available solutions, whilst shaping the strategy and product development for future technology.

We believe that the adoption by the UK health service and its supply chain, of the above recommendations is essential if the current levels of patient deaths and adverse reactions through medication errors and inefficiencies in supply chain operation are to be substantially reduced. People's lives are at stake together with millions of pounds of taxpayer's money.

Many industries have already adopted elements of the recommended solutions throughout their supply chains increasing supply chain efficiency and delivering substantial cost savings. These are tried and tested solutions found in every day life and leveraged throughout the world.

Certain areas of the UK pharmaceutical supply chain have already adopted the use of these recommendations (92% of pharma products already carry an EAN code). Whilst we recognise there will be an initial investment, experience from other industries demonstrates that the benefits will far outweigh the costs.

It is this group's recommendation that the UK seize the opportunity to take a leading role in the development of European / Global policy, complementing the government's agenda to deliver change and improvements in the NHS.

2 Introduction

The pharmaceutical industry's supply chain, from manufacturer to patient, is highly fragmented and makes little use of automatic identification and data capture techniques, such as bar coding and RFID. As such, it can learn from and leverage experiences from other leading industries (the retail, automotive and other sectors), which have transformed their supply chains reaping huge efficiency and security benefits using such automated techniques.

Representatives from all key areas in the UK pharmaceutical supply chain have come together as a cross-industry working group to discuss and agree on a mutually beneficial strategy that will ultimately deliver improved patient safety and supply chain efficiency. This document is the result of their work.

The purpose of this document is to make firm recommendations for product identification and coding having accounted for the issues and needs of the various participants in the pharmaceutical supply chain in order to deliver improved patient safety and supply chain certainty through the application of appropriate technology.

The objectives of this cross-industry working group

1) Capture and consolidate industry and industry influencer's views on product identification.
2) To embrace global, open identification standards.
3) To gain consensus and commitment from these far reaching groups on the recommendations and conclusions.
4) Build a long-term approach with a clear migration path that ensures the technology investment is future proofed.
5) Address barriers to implementation, considering current practice and technology options.
6) To make recommendations for industry and profession mandation for the adoption of product / supply chain identification and coding standards in the interest of patient safety and supply chain efficiency.

The scope of the work only covers marketed pharmaceutical products in the UK supply chain, from manufacturer to point of use, with the inclusion of track and tracing at different product packaging levels. Other supply chain routes to patient, such as named patient and clinical trials, fall outside of this scope but should not be forgotten in the longer-term strategy for product identification needs.

The UK is not to be seen in isolation and should be mindful of other health supply chain initiatives from around the globe. This group has referenced information, notes, reports and presentations from various sources in the compilation of this document.

This document supports policy makers in the UK and may be of interest to a wider European and global audience.

The target audience for this document is:

Department of Health and associated agency policy decision makers.
Pharmaceutical manufacturers.
Pharmaceutical distributors
Pharmacists (retail and hospital)
National Programme for IT (NPfIT)
Chief Information Officers (Hospital Trusts)
Pharmacy system suppliers
Medical consumable and device suppliers
And other decision makers within the pharmaceutical supply chain

3 Benefits of coding standards

3.1 Improved Patient Safety

The certainty of identification of pharmaceutical products enabled by scanning will reduce medication errors by the elimination of error-prone manual processes thereby saving peoples' lives.

Linkage of accurate product information to the patient's electronic patient record will deliver even greater safety benefits – ensuring the right product, to the right patient, at the right dose, at the right time, by the right route.

The goal is to support zero medication errors in all healthcare environments.

3.2 Anti counterfeiting

Product safety is a key issue for the pharmaceutical industry and the security of the total supply chain. The risk of counterfeit products is highly detrimental to patient safety and security of the brand.

The ability to secure the product from tampering or be able to identify and remove counterfeit product from the supply chain will ensure that the patient does not receive a potentially lethal medication. Counterfeit products enter the UK supply chain through many routes sometimes without the supply chain being aware. The development of batch / serial traceability through bar codes and RFID/EPC (Radio Frequency Identification/ Electronic Product Code) will greatly enhance product security and supply chain response to counterfeiting.

3.3 Operational Efficiency Gains

Accurate tracking of products within the supply chain allows transparency and traceability. All transactional processes (from ordering and invoicing to product recalls, enquiries about availability, prevention of errors, patient administration) would be immeasurably improved. In other supply chains not dissimilar to pharmaceuticals e.g. fast moving consumer goods, vast savings have been reported in inventory costs, capital tied up, administration costs and replenishment lead times e.g. from days to hours.

3.4 Economic Gains

The benefits of improved patient safety and operational efficiency drive additional economic benefits. These include reduction in reworking and reordering, improved product availability, reduction in waste (exceed expiry date), reduced compensation claims, lower litigation costs and better bed/patient throughput (less bed days lost due to adverse events).

Accurate product identification and traceability reduces the opportunity for supply chain leakage, presence of counterfeit drugs and potential for NHS fraud.

4 Drivers for change

4.1 Patient Safety and Drug Administration Error Facts

Today 50% of the estimated 72,000* deaths in the NHS are caused by medication errors overall. 34% of all medication errors that cause problems for patients are associated with drug administration. Many of the medication errors occur as a result of a lack of machine-readable codes, which significantly increases the risk of human visual identification errors (Many packs are of similar name, size and appearance).

Patient safety is a key political issue for the UK Government (as well as the European Commission). Authoritative reports such as '*When Errors Happen'* (Bates et al) and recent UK reports such as '*A Spoonful of Sugar'* (Audit Commission) and '*Organisation with a Memory'* (Department of Health) have underlined the extent of medication errors. Killing people in hospitals, where patients should be very safe, is just not acceptable.

The NHS has recently calculated that approximately 60 patients die each day due to adverse drug errors.

As *A Spoonful of Sugar* also identified, the knock on costs of a high patient risk environment leads to significant costs in additional hospital stays plus clinical negligence claims.

For example:

- Adverse events cost approximately £2 billion a year in additional hospital stays alone.
- The NHS pays out every year around £400 million settlement of clinical negligence claims.

*National Patient Safety Agency (NPSA) - Medication error stats. See also Appendix

4.2 Automation

A growing number of dispensaries within hospitals and primary care are moving towards robotic picking machines. These machines are currently driven by globally recognised, standard barcodes (the EAN.UCC System) that identify where the goods are stored within the robot and retrieved for dispensing.

4.3 Underpinning the National Programme for IT (NPfIT)

Standardised product coding, data structures and data carriers will ensure interoperability throughout the supply chain as well as within the clinicians' IT systems. Using one open, global standard for product and patient identification at the core of these systems will enable the certain link between the physical product and the electronic patient record. As such, these standards are critical to the successful roll out of the NPfIT programme.

4.4 dm+d (dictionary medicines + devices)

dm+d is a database for all medicines and medical devices used in primary and secondary care designed to support the development of the electronic health record and as such is a key component of the NPfIT programme. Its central coding system (SNOMED) is not a pack identifier and is not recognised by supply chain processes in or outside hospitals. NPfIT are recommending adoption of the EAN.UCC System to provide the necessary supply chain linkage.

4.5 International Developments

4.5.1 USA - Food and Drug Agency (FDA) decisions on pharmaceutical coding (CFR21 parts 201, 606 & 610)

The FDA is a key influencer of the global pharmaceutical market. On 26th April 2004, the FDA published a rule that requires certain human drug and biological product labels to have a linear barcode. The rule being confirmed, major pharmaceutical companies are already well advanced adopting it. Additionally, the FDA is recommending the use of RFID technology to combat counterfeit products from 2007. http://www.fda.gov/

4.5.2. Other countries

Use of a standard coding system (the EAN.UCC System) for pharmaceutical product identification is mandatory in Australia and in Japan for pharmaceuticals (2nd largest global market to the US) as well as for medical devices (both the EAN.UCC System).

In Europe, the lack of harmonisation of coding systems across Member States has led to a number of national regulators to adopt their 'proprietary' methods for coding to protect against national risks which are proving to be implementable by industry at best at high cost, or at worst not implementable at all. Relevant examples are Belgium (legislation EN011934), Italy legislation Ministry Of Health law no. 39 (Bellini label for anti-counterfeiting) and Portugal (requirement to include batch numbers in the code).

EAN International's *European Healthcare Initiative* and its European Pharmaceutical Supply Chain project is currently very active, aiming to introduce harmonisation of identification and coding standards using the EAN.UCC System across Member States. See Appendix 7.4 or www.ean-health.net for more information.

4.6 Manufacturer developments

Attempts by manufacturers to intercept international legislative developments, particularly the FDA rulings, has led to the introduction of a number of 'proprietary' coding systems being introduced onto the market thereby increasing supply chain fragmentation.

4.7 NHS PaSA Announcement

The NHS Purchasing and Supply Agency (NHS PaSA) has very recently published a strong recommendation for the adoption by industry of the open, global standards of the EAN.UCC System for the identification and coding of pharmaceutical products and medical devices. (See Appendix for more information).

5 Current status

5.1 Coding

92% of pharmaceutical drug packs contain an EAN.UCC barcode (EAN 13) on the product pack. The current gaps include clinical trials, specials, hospital own manufactured items and parallel imports. The EAN 13 code contains fixed information (Country, Company, Product and a check digit), which means it can be produced and printed when the product pack artwork is commissioned. From a manufacturer's perspective the effort to adopt EAN13 would be relatively straight forward as most already apply this coding standard.

As the codes used are based on the global, open standards of EAN.UCC they are globally unique, ensuring product identification integrity that is critical to supply chain efficiency and patient safety.

5.2 Supply chain processes

Downstream from the manufacturer there are different routes to the patient that are less transparent in terms of capturing product identification (e.g. named patient, homecare and clinical trials). By the adoption of one standard method for product identification there is an opportunity to reduce medication errors and streamline the supply chain, but for these benefits to be realised there needs to be consistency of application.

Speed and error are the main pressures in the wholesaler with systems picking up to 10 items a second. Full line wholesalers make 235,000 deliveries per week in the UK to dispensing GP's, hospitals and community pharmacies (a British Association Pharmaceutical Wholesaler statistic). Therefore an automated process of data capture will improve accuracy and speed.

In the community pharmacy another system is generally employed for ordering and receipting of goods using the PIP code. This system is manually orientated (non machine readable). Some pharmacies use the EAN code for EPOS (Electronic Point of Sale) benefits. Ethical products are normally ordered and delivered twice daily in single units. This helps to minimise stock levels. The downside is that deliveries need to be checked manually where the EAN codes are not used.

Current processes in hospital pharmacy can be manual and labour intensive. In some of the more technologically advanced pharmacies, goods are ordered via bespoke and individual pharmacy systems with some electronic transfer of orders and invoices, and even in these cases, the systems require manual checking. Goods are often ordered generically but supplied by brand, which can give rise to confusion. If the use and transference of EAN.UCC codes were employed this issue would be greatly reduced.

Traditional distribution systems in hospitals are manual and lead to an unacceptably high level of transcription picking, ordering and invoicing errors that take time to sort out and are potentially harmful to patients. However there is increasing investment in electronic systems, automated picking and administration systems being adopted. The huge investment in IT systems being delivered by NPfIT will accelerate this process. Hospitals are starting to refuse packs without a machine-readable product identifier.

6 Conclusions and recommendations

The overwhelming conclusion of this group is that the coding solution should be consistent throughout the supply chain and compliant with open, global coding standards.

Based on our research, and that of others (British Healthcare Trades Association, Hospital pharmacy etc.), the standard of choice is EAN.UCC consisting of:-

- identification and data structure;
- data carriers (symbology and technology) which specifically include
  - Barcodes
  - Radio Frequency Identification (RFID) in the form of EPC (Electronic Product Code)
  - and encompassing a migration path to future coding symbologies

The recommendations below, provide a migration path from a standardised platform using available technology through to a future technological solution for product identification. As such the recommendations should be viewed in their entirety and not in isolation.

6.1 Recommendation One for review

There is a need for a general process and practice review to address safety issues. These are:

- Scanning product at the point of use / administration
- Review of broken pack dispensing and implications such as the loss of the product code from the pack.
- For each trading partner to support traceability throughout the supply chain there is a need to communicate and capture the product identification (GTIN), batch (in specific instances, serialisation) and expiry date.

Note: Supply routes such as clinical trials and named patient supply are out of the scope of the phasing below and require more in depth review.

6.2 Recommendation Two for mandation

The formal adoption and implementation of the EAN.UCC System standards for all pharmaceutical products available in the end-to-end UK supply chain

6.2.1 Adoption of a single code standard for the identification of pharmaceutical products

- Consumer /item pack level
  - EAN 8, EAN 13 encoding the GTIN*
  - For small packs (Vaccines) RSS encoding the GTIN
- Outer case level
  - EAN 128 encoding GTIN, Batch number and Expiration code*
- Pallet / logistics level
  - EAN 128 encoding the Serial Shipping Container Code (SSCC).*

6.2.2 Prohibit the re-use of pharmaceutical product codes anywhere in the supply chain from patent to patient. Any product variation*** will require a new unique code as defined by EAN global standards.

6.2.3 Development of appropriate documented guidelines to meet the requirements of the above.

* See Glossary of Terms

*** Refer to EAN.UCC globally specs “When to change a GTIN”

6.3 Recommendation Three for a Joined-up Work Programme

Formalise the immediate formation of a Government (Department of Health) sponsored joined-up (industry, Government / NHS) work programme to undertake the following:

- Evaluate options to encode pharmaceutical product information including the batch number, serial number and expiration date.
- Evaluate options to encode medical device and supplies product information including the batch number, serial number and expiration date. Composite code / Data Matrix for additional information.
- Review packaging coding levels once the consideration of different dosage forms in conjunction with the need for and acceptance of broken pack dispensing has been concluded.
- Consideration of unit of dose identification
- The adoption of RFID / EPC is seen as inevitable in this sector and plans to pilot the technology are already underway. As a consequence, RFID / EPC may be adopted at an early stage as it is a recognised solution for track and trace down to item level (single instance). However; the technology standards are still being finalised and there are some technological limitations to be addressed. EPC is an extension of the recommended EAN.UCC System standards.
- To develop appropriate guidelines to meet the requirements of the above
- To formulate a recommendation for mandation of the output from the above.

7 Appendix

7.1 Patient Safety – Facts and Figures

7.1.1 ***'When Medication Errors Happen'*** (Bates et al): JAMA1998. 280 No.15 (21 October) identifies the following error rates:

- Prescribing 56%
- Administration 34%
- Dispensing 4%
- Transcription 6%

7.1.2 ***"A Spoonful of Sugar"*** (Audit Commission Report), gave the following statistics that have been multiplied up to illustrate the national picture:

In average District General Hospital (DGH) there are:

- 7000 drug administrations per day.
- The error rate is about 5% (varies between 3% and 10%).
- In an average DGH there are 350 errors per day from administration alone.
- Some of these cause adverse drug events (ADEs), which increase the length of stay in hospital by on average 8.5 days (Vincent BMJ). BMJ 2001;322:517-519 (3 March)

It is hard to determine what proportion of errors cause ADEs – however -

- **1 in 1000 of all administration errors is potentially fatal.**
- So the average DGH potentially kills 1 patient every 3 days from administration errors
- Or for England with approximately 180 DGHs that's 60 patients per day.

7.1.3 ***"An Organisation with a Memory"*** Department of Health (2000) stated:

In supporting patient safety the following aspects are considered pre-requisites for a safe and secure supply chain.

- Adverse events occur in around 10% of admissions
- There are an estimated 850,000 adverse events a year.
- Adverse events cost approximately £2 billion a year in additional hospital stays alone.
- The NHS pays out every year around £400 million settlement of clinical negligence claims.
- Medication errors accounts for around a quarter of the incidents which threaten patient safety

7.2 Regulation – The Food and Drug Administration

FDA decisions on pharma coding (CFR21 parts 201, 606 & 610)

In the federal register of March 14, 2003, the FDA published a proposed rule that would require certain human drug and biological product labels to have a linear barcode and invited comments from stakeholders.

The requirement was for barcodes on the labels of:

- All human prescription drug products, excluding samples
- Biological products (including vaccines)
- OTC (Over The Counter) drug products that are commonly used in hospitals.

Following the yearlong consultation the FDA has issued a new rule to require certain human drug and biological product labels to have bar codes. The bar code for human drug products and biological products (other than blood, blood components, and devices regulated by the Centre for Biologics Evaluation and Research) must contain the National Drug Code (NDC) number in a linear bar code.

This rule became effective on April 26, 2004. Drug products that receive approval on or after the rule's effective date must comply with the bar code requirement within 60 days after the drug's approval date. Drug products that received approval before the final rule's effective date must comply with the bar code requirement within 2 years after the final rule's effective date.

7.3 dm+d (Dictionary of Medicines and Devices)

- The purpose of the NHS dm+d is to underpin the NHS master files and provide the single terminology standard that will form the UK drug extension to SNOMED CT (clinical terms). Together these will provide the basis for electronic and human readable representation of all healthcare information, which will be contained within electronic health records in the NHS and beyond.

- The plan is for the Dictionary of Medicines and Devices to become the NHS standard dictionary for all products used in clinical messages and care records. The NHS Information Standards Board and the Technical Office of the National Programme endorse this approach for Information Technology. This will ensure no ambiguity in meaning for product use in the clinical setting and the correct use of product for a particular clinical condition. The dm+d is owned by the NPfIT and partnered by the PPA.

- There is a need to map the EAN.UCC code for the particular product pack to one of the concept classes of the dictionary. This concept class would be AMPP Actual Medicinal Product Pack, where the supplier, the active ingredient, the strength and the pack size are all defined or inferred from related concept classes. The mapping will be distributed as part of the dm+d.

- It is proposed that any solution for England would be adopted by the Home countries, to prevent any confusion about the requirements from the manufacturers. Scotland has already specified dm+d as a terminology standard, while Wales are close to confirming their adoption.

- Clinicians should notice little change from current presentations. Auto-Identification technology would be present, to read the EAN code in the most appropriate Symbology. This is currently an EAN-13 barcode. Closed loop administration could then be facilitated, to check that the product is the correct one for that patient, and that the patient has the condition that the product is licensed to treat, warning the clinician if this is not the case.
  For more information refer to Pharmaceutical Journal volume 273 7th August 2004 "What is the dm+d and what will it mean for you and pharmacy practice?"

7.4 The European Pharmaceutical Supply Chain Initiative (EPSCWG)

The European Pharmaceutical Supply Chain Working Group (EPSCWG) is an EAN International *European Healthcare Initiative* project that is aiming to establish a set of voluntary Guidelines for identification, bar coding and eMessaging for the European pharmaceutical industry based upon the EAN.UCC System. Having developed these Guidelines, for the industry by the industry, they will be promoted as the 'best practice' model to regulatory bodies (e.g. European Commission, EMEA) as well as pharmaceutical companies and organisations.

During 2004, a Task Force will complete a workplan that will review existing EAN International documentation describing guidelines and eMessaging specifications developed by EAN International for the healthcare industry. Any suggested enhancements to these guidelines will be submitted to EAN International's GSMP (Global Standards Management Process) change control procedure. The target is to start piloting the proposed guidelines in Q1 2005.

Company representatives and industry experts are involved in the project representing all functions of the supply chain. These include branded, generic, and OTC product manufacturers, pre-wholesalers, full-line wholesalers, community and hospital pharmacists, across a broad geographical cross section of the European pharmaceutical industry.

It is important that the EPSCWG and UK PSCWG projects are aligned for maximum leverage as the objectives are very similar. Ideally, the related workplans for both will remain aligned. It is likely that the EPSCWG project deliverables can feed into PSCWG for market testing in the UK.

7.5 NHS PaSA justification for adopting EAN.UCC

The first step in the decision process was for PASA to choose the coding environment that best suited the NHS community. The four options defined are based on the combination of identifiers (ISO or non-ISO) and control system (closed or open).

Option 1: Proprietary (non-ISO) identifiers – Closed system
Option 2: Many global identifiers – open system
Option 3: One global identifier – Closed system
Option 4: One global identifier – Open system

Option 1: Proprietary (non-ISO) identifiers – Closed system
i.e.: NSV (National Supplies Vocabulary)
PIP (Pharmaceutical interface products code)

Where organisations create their own code structure, they destroy the possibility of uniquely identifying products throughout the supply chain. This option also requires the organisation that dictates the code to maintain the system and to police its use in the supply chain. Therefore it is applicable only in supply chains completely managed by the customer (or distributor). Additionally, proprietary identifiers are not interoperable with other identifiers and cannot be communicated with non-compatible systems.

The message is: Suppliers Should Not Invent Their Own Code Structures

Option 2: Many global identifiers – open system

Interleaved 2of 5
EAN.UCC
Code 39 and HIBCC
Code 128
PDF417
Maxicode
DataMatrix
QR Code

in the NHS

Where organisations allow multiple standards they complicate the message to suppliers about one code throughout the supply chain and force suppliers down the route of standards comparison and evaluation many times over. By allowing many standards to specialise in different supplier groups, there is also a possibility that standards may develop into proprietary: i.e.: the healthcare standard or the car manufacture standard, which are not inter-operable and carry different sets of data.

The message is: Standardise Code Structures

Option 3: One global identifier – Closed system

I.e.: EAN in Marks & Spencer
NPC represented with Interleaved 2 of 5 in NHS Logistics and the NHS

This option applies to organisations that have complete control over their total supply chain from point of manufacture through receipt to point of use.
Where organisations decide to standardise on one global code structure but keep the copyright and royalties of the identifier to themselves, they repeat Option 1.

The message is: Suppliers Should Control and Manage Their Own Codes

Option 4: One global identifier – Open system

I.e.: EAN.UCC in Tesco, Asda and elsewhere in the retail sector
EAN.UCC plans in Pharmaceuticals Industry

Where organisations decide to standardise on one open global code structure and ask that all their suppliers comply with the decision, life for suppliers and customers is straightforward: they can communicate their requirements (requisitions, orders, delivery notes, invoices) in a common language and they can expect their items to be identified in a standard format. The biggest advantage is that Option 4 is an “all systems go” situation for suppliers who can buy a standard solution package and open to their business doors to new opportunities.

The message is: There should be one Global Coding Standard For All Suppliers Controlled and Managed by Suppliers themselves.

PASA has decided that Options 1,2 and 3 are not conducive to the needs of the English NHS and therefore recommends the adoption of Option 4 for all suppliers.

1. *Comparison & evaluation of global coding standards*

PASA needed an objective mechanism to compare and evaluate the different ISO standards for coding and data carrier technologies. This mechanism was provided by CIPS* set of criteria for "Maximising Returns from Purchasing Data"* through item classification and codification.

The standards below are for data carrier standards which may represent specific or variable data structures (product codes with specific characters and minimum - maximum number of characters). Among them, only EAN or UCC and HIBCC can be truly unique globally as the code structure and actual code numbers are controlled by central organisations. Without central control, there is no guarantee that codes are unique and immediately recognisable (Criterion 2).

The table below compares and evaluates the different ISO coding and data carrier standards against the CIPS standards:

EAN.UCC because…

NHS PASA recommend the use of EAN.UCC in the English NHS because it is the one standard out of all other ISO standards that satisfies the criteria that PASA decided was key to selection. Specifically, EAN.UCC is:

1. Available in linear symbology, which is the most widely used anywhere in the world.
2. A unique and secure numbering system.
3. ISO accredited.
4. Present in UK for resolving any type of customer query.
5. A consistent code structure, immediately recognisable.
6. Independent and a not-for-profit organisation, found for the benefit of companies of any size, anywhere in the world.
7. Here to stay, with 1m users, 5bn transactions per day in 129 countries with future proof: ebXML, RFID,RSS and plans: EPC, two-dimensional symbology.
8. Code structure is numeric and non-significant, and therefore can apply to any industry.
9. Already present in many different sectors in the manufacture, retail and healthcare.
10. Integrated with many types of data carrier: bar code, RSS, RFID depending on application.
11. Widely available throughout the supply chain for any type of company so that total cost of implementation and integration is minimised.
12. Available at a standard cost which includes active support for companies that wish to implement it or migrate from other codes.
13. Available at a standard cost and inherently supports code integrity (failsafe code structure).
14. Is immediately compatible with current systems and has a failsafe element: Optical Character Recognition part for use even without reading scanners.
15. Built on the simple element of product identification with the choice of associated attributes being attached to the basic code in an identifiable way.
16. The standard of choice of an overwhelming number of suppliers nationally contracted by NHS PASA as a research conducted by NHS PASA in 2003 shows:

* The Chartered Institute of Purchasing and Supply. Maximising Returns from Purchasing Data. November 2002. http://www.cips.org/downloads/Professional%20Resources/Overview/codingclass.pdf

- Pharmaceuticals: 80 (23%) of the 278 PASA suppliers of pharmaceutical products responded. The results were:
  - 64 suppliers (80%) use or plan to use bar codes in their operations. Of these suppliers:
    - 92% use EAN or UPC
    - 3% use HIBCC
    - 5% use other codes.
  - 12 suppliers (15%) do not use nor plan to use bar codes in their operations
  - 4 suppliers (5%) were distributors and answered Not Applicable.
- Healthcare & Non-healthcare (excluding Pharmaceuticals): 468 (48%) of the 982 PASA suppliers of non-pharmaceutical products responded. The results are:

  - 239 (51%) use or plan to use bar codes in their operations. Of these 235 suppliers:
    - 74% use EAN or UPC
    - 8% use HIBC
    - 8% use other codes
    - 10% don't know what they use.
  - 229 suppliers (49%) do not use nor plan to use bar codes in their operations.

7.6 Key Stakeholders

Key stakeholders in the UK pharmaceutical supply chain are identified as:

- Patients
- Clinicians
- Corporate HQ
- Manufacturers
- Wholesalers
- Parallel Importers
- Retailers
- Community pharmacies
- Hospital pharmacies
- Logistics and transportation
- Trade associations
- Government and associated agencies including
  - DoH and Arms length bodies MHRA, NHS PaSA, NPSA, PPA
  - Home office

Glossary of Terms

AIDC	Abbreviation for Automatic Identification and Data Capture.
Brand owner	The party that is responsible for allocating EAN•UCC System numbering and bar code symbols on a given trade item. The administrator of an EAN•UCC Company Prefix.
Data carrier	A means to represent and scan data in a machine readable form.
Data Standard	The entirety of all EAN•UCC System data standardised in meaning and structure.
Data structure	EAN International data structures defined in the various lengths required for the different identification purposes, which all share a hierarchical composition.
EAN	European Article Number - Open Global data standards for product, patient, location and asset ID.
EAN International	EAN International, based in Brussels, Belgium, is an organisation of EAN Member Organisations that manages the EAN•UCC Standards. http://www.ean-int.org/
EAN Member Organisation	A member of EAN International that is responsible for administering the EAN•UCC System in its country (or assigned area) and for managing the correct use of the EAN•UCC System by its member companies.
EAN/UCC System	The specifications, standards, and guidelines administered by EAN International.
EAN/UCC-13 Data Structure	13-digit data structure composed of an EAN•UCC Company Prefix and Check Digit as well as an Item Reference.
EAN/UCC-8 Data Structure	8-digit data structure composed of an EAN/UCC-8 Prefix, Item Reference, and Check Digit.
EAN/UPC Symbology	A family of bar code symbols including EAN-8, EAN-13, UPC-A, and UPC-E Bar Code Symbols. Although UPC-E Bar Code Symbols do not have a separate Symbology Identifier, they act like a separate symbology through the scanning application software. See also EAN-8 Bar Code Symbol, EAN-13 Bar Code Symbol, UPC-A Bar Code Symbol, and UPC-E Bar Code Symbol.
EPC	Electronic Product code – normally encoded using globally recognised RFID technology standards EPC Global
EPC Global	Global data standards for RFID technology managed by EAN member organisations http://www.epcglobalinc.org/
EPOS	Electronic point of sale
FDA	Food and Drug Administration http://www.fda.gov/
Global Trade Item Number™	A Global Trade Item Number™ may use the EAN/UCC-8, UCC-12, EAN/UCC-13, or EAN/UCC-14 Data Structure.
GTIN™	Abbreviation for the Global Trade Item Number™.
Logistic unit	An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with an SSCC.
PIP code	An interim human readable coding method for pharmacy products. Used in the transmission of order information between pharmacy and wholesaler (and others). Jointly owned by NPA and Chemist and Druggist.
RFID	Radio Frequency Identification – Microchip and antenna queried by a radio frequency reader providing structured identification information when using EPC Global standards
RSS	Reduce Space Symbology linear barcode
SNOMED CT	SNOMED Clinical Terms® universal healthcare devices and medicines terminology. http://www.snomed.org/
SSCC	Term used for the Serial Shipping Container Code. The unique identification of a logistic unit using an 18-digit data structure.
Symbol	The combination of symbol characters and features required by a particular symbology, including Quiet Zone, Start and Stop Characters, data characters, and other auxiliary patterns, which together form a complete scanable entity; an instance of a symbology and a data structure.
Symbology	A defined method of representing numeric or alphabetic characters in a bar code; a type of bar code.
Trade item	Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain.

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AAH Pharmaceuticals	
ABPI	Association of British Pharmaceutical Industries
Alpharma	
BAEPD	British Association of European Pharmaceutical Distribution
BAPW	British Association Pharmaceutical Wholesaler
BGMA	British Generic Manufacturers Association
Boehringer Ingelheim	
Boots Plc	
e.centre (GS1 UK)	Global Standards 1 (from 2005)
European Healthcare Initiative	
National Pharmacy Supply Group	
NPfIT	National Programme for IT
NPA	National Pharmaceutical Association
NHS PaSA	NHS Purchasing and Supply Agency
PPA	Prescription Pricing Authority
UniChem Ltd	

References

Documents that have been referenced in writing this document

Reference initiatives/legislation:
European PSCWG (France and Ireland also setting up similar groups)
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