

### **GS1 Healthcare Provider Advisory Council Webinar**

11 September 2014





#### This is the 7th Webinar

- Bar coding medicines to the single unit administered in hospitals: EAHP's work towards a solution
- Richard Price, Policy and Advocacy Officer, European Association of Hospital Pharmacists



 Webinar will be available here: http://www.gs1.org/healthcare/hpac\_webinars



# Bar coding medicines to the single unit administered in hospitals: EAHP's work towards a solution



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#### **Outline of Presentation**

- About EAHP
- Context of the single unit bar code request
- The overriding patient safety case
- Other benefits from bar coding to the single unit
- Overcoming the barriers
- October 2014 Leuven event
- Take home messages
- More information



#### Who are EAHP?

- European Association of Hospital Pharmacists
- Founded in 1972
- Represent c.21,000 hospitals in 34 countries
- Hold an annual Congress
- Publish a Journal, EJHP, x6 a year
- Educational opportunities
- Advocate on key issues







# CONTEXT TO THE BAR CODE TO THE SINGLE UNIT REQUEST









#### Context to the bar code to the single unit request

#### What do we mean by the single unit?

Recently agreed GS1 global definitions:

Single Unit	Single item of medicine/Medical device without any package, for example the single tablet in a blister or bottle, the syringe as such.	
Single Unit Package (GS1 primary package)	Package that contains one discrete pharmaceutical dosage form. i.e. a tablet, a certain volume of a liquid or that is the immediate package for a medical device like a syringe	Oww.ft online de Bider./Image no. 3867379



#### Context to the bar code to the single unit request

## Primary packaging of the single unit of medicine administered in hospitals







The single item of medicine in an individual packaged component could for example include:

- the single medicine within a perforated multi-dose blister pack; or,
- a syringe, a vial or an ampoule



#### Context to the bar code to the single unit request

The call for bar coding of medicines to the single unit has been a central EAHP policy aspiration since 1987

The policy was renewed and updated in 2007, 2010 and 2012

ASSOCIATION EUROPEENNE DES PHARMACIENS DES HOPITAUX

RECOMMANDATIONS POUR LA PRESENTATION UNITAIRE DES MEDICAMENTS

#### 1. Introduction

Il est nécessaire de définir les besoins et les souhaits des pharmaciens hospitaliers européens. Ce document est rédigé dans le but d'attirer l'attention, en particulier de l'industrie pharmaceutique, sur l'importance de la présentation unitaire, support d'une dispensation contrôlée en milieu hospitalier.

#### Définition

La présentation unitaire d'un médicament est la présentation appropriée d'une unité déterminée de ce médicament dans un récipient unidose, destinée à l'administration en une seule fois au patient. Il est souhaitable que l'unitécommune de dispensation soit la plus proche possible de l'unitécommune d'administration.

#### Formes pharmaceutiques concernées

La définition précédente s'applique à la quasi-totalité des présentations et est directement applicable aux formes suivantes :

- formes orales sèches (comprimés, dragées, gélules, poudres,...)
- formes orales liquides ou gélifiées à posologie définie (sirop, potions, émulsions, ...)
- formes injectables
- formes rectales
- formes locales (voies on htalmique, oto-rhino-laryngologique, vaginale, ...)
- formes dermatologiques liquides ou pâteuses.

#### 4. Buts

DELIVRER FT ADMINISTRER LE BON MEDICAMENT AU BON MALADE, PAR LA BONNE VOIE D'ADMINISTRATION AU BON MOMENT. AU BON DOSAGE.



#### Main request

Unit doses blisters, with each single dose containing the whole information

- Trade name
- Active substance
- Dosage
- Expiry date
- Batch number
- Barcode
- Including product ID, expiry date and batch number
- Use of a recognized international standard (i.e GS1)
- Datamatrix



#### Bar coding to the single unit

# The overriding patient safety case









#### The patient safety case for bar coding to the single unit

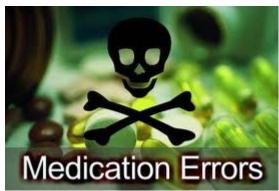
#### The importance of the final check at the bedside

 Medication errors are one of the most common causes of preventable adverse events in the healthcare system



 A <u>complete</u> identification of the medicine, <u>up to its point of administration</u>, is therefore a key element of safe medications practice and ensuring:

Right medication, right dose, right patient, right time, and right route





#### The patient safety case for single unit bar coding

#### The 1999 IOM 'To Err is Human' Report

- Report concluded that between 44,000 to 98,000 people die each year as a result of preventable medical errors, with <u>7,000 due to</u> medication error
- Later, in 2006, IOM estimated medication errors cost <u>3,5 billion dollars</u> in the US, according to conservative estimation
- IOM has recommended <u>process automation</u> as a way of preventing errors, or adverse events.







#### The patient safety case for bar coding to the single unit

#### **America takes action!**

- In 2001 the <u>Federation of American</u>
   <u>Hospitals (FAH)</u> called for bar coding to the single unit
- The National Coordinating Council for Medication Error Reporting and the American Society for Health System Pharmacists supported the call
- 2006 campaign success! The US FDA made it mandatory for medicines supplied to hospitals to be bar coded to the single unit.







#### The patient safety case for bar coding to the single unit

#### Why did the FDA do it?

- FDA estimated that hospitals could reduce medication error rates by as much as <u>85%</u> from bedside bar code scanning
- A study conducted at a Veterans Affairs Medical Center of barcode scanning systems, noted the system helped administer
   5.7m doses of medication without medication errors.
- FDA also estimate bar code rule will prevent nearly <u>500,000</u>
   <u>adverse events</u> and transfusion errors over 20 years.
- The economic benefit of reducing health care costs, reducing patient pain and suffering, and reducing lost work time due to adverse events is estimated by the FDA to be \$93 billion over the same period.



## The patient safety case for bar coding to the single unit **Meanwhile**, in Europe...

 After "To Err is Human" Council of Europe commission a Group of Experts to advise on the management of patient safety and prevention of adverse events



 2006 report makes clear recommendation, national and European legislative framework should "require complete and unambiguous labelling of every single unit of use of all licensed medicines products (e.g. tablet, vial & nebules), including the INN, trade name, strength, expiry date, batch number and a data matrix bar code." NOT YET ENACTED





# Other benefits to recognise Recalls, assuring against counterfeit, managing information and the ageing society,









#### Assisting in the recall of medicines

- Nature of medicines use in hospitals means that drugs which are dispensed in multiple blisters often have to be <u>cut</u>, <u>separated and</u> <u>spilled</u> out from their original blister package
- Without a bar code, information may be absent from the individual unit of medicine and an accurate control at the bedside is not feasible
- Bar coding to the single unit would make traceability of the individual unit of medicine possible







## Providing further assurance against potential counterfeit intrusion

 There are numerous points in the supply chain between manufacture and administration where unscrupulous individuals can divert and replace legitimate medicine



 Bar coding to the single unit of medicine for use in hospitals can help to provide a further visual assurance of the legitimate nature of a medicine, or its potentially suspect origin if discovered within the community or other parts of the medicines supply chain.





## Supporting comprehensive management of medicines information

- Accurate information about how medicines are used increasingly important in a costconscious health environment
- Including in what dose forms and for what conditions
- Bar coding to the single unit of medicine for use in hospitals offers new possibilities of understanding and knowledge about overall medication use







#### Preparing for an ageing society

- Large increase in elderly population, associated with <u>multi-morbidities</u> and <u>polypharmacy</u>
- Heightened risk of medication error occurring, and the risk posed by error
- Bar code scanning at administration key tool in meeting the challenge
- Bedside scanning not only useful for hospital, also nursing & residential homes







#### Bar coding to the single unit

# Overcoming the barriers to implementation









#### Working together as one

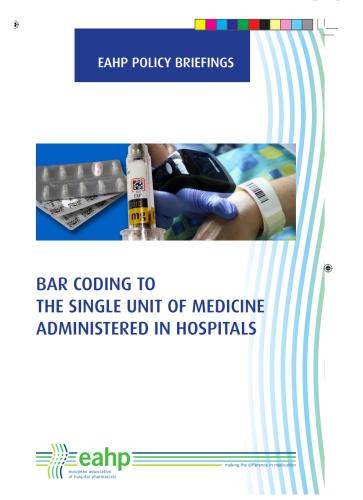
#### October 2014 Leuven event

- Brought together patient groups, healthcare professionals, industry representatives to see bedside scanning in practice, examine the evidence and discuss the way forward
- Concluded that a wide partnership was required – more than hospital pharmacy and industry
- Activity with EFPIA and others to form a working group scheduled to take place





#### Other new materials



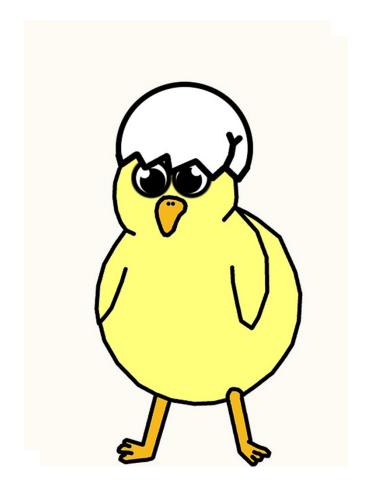


http://www.eahp.eu/practice-andpolicy/bar-coding-medicines-tothe-single-unit/



#### Falsified Medicines Directive: a start not an end

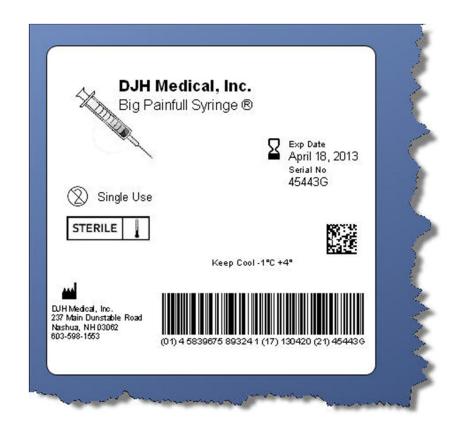
- Scanning practices and technology in European hospitals set to become even more widespread, if not universal (2017 implementation)
- Addresses the "chicken and egg" problem of bedside scanning which comes first, hospital technology or the bar code?
- Important that FMD not seen as the end of the process – the start





#### Medical Devices Regulation: another factor

- Will require UDI systems for medical device traceability in Europe – from manufacture to patient use
- Further impetus to drive scanning technology uptake and practice in European hospitals
- Discussions with industry and EAHP taking place about the single unit aspects – also an issue for devices





#### Advancement of mHealth and eHealth

 mHealth and eHealth raises the prospect in further accessibility to the benefits of scanning technology

 E.g. promotion of patients conducting scans of medicine with mobile devices in order to get medicines information

 Benefit of single unit bar coding added to – the prospect of lost outer packaging etc





# Bar coding to the single unit of medicine

#### Conclusions









#### **Take Home Messages**

- The patient safety benefits of bedside scanning in hospitals have for too long been held back by a simple but difficult barrier – no bar coding to the single unit for medicines
- Industry, GS1, hospital pharmacy are working together on meeting the single unit bar coding challenge – more news soon we hope
- Legislative, cultural, technological and international trends are moving in favour of the achievement of single unit bar coding and the prospect of systematic bedside scanning in hospitals across Europe may be moving closer
- Pioneers, champions, awareness raisers, and evidence gatherers are still required however!



#### Small advertisement....



#### Synergy Satellite Breakfast event

Thursday 26<sup>th</sup> March 2015

**HAMBURG** 





#### Thank You!

#### **Further information**

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#### **QUESTIONS & ANSWERS**

Please use question panel to type in questions







#### Innovative National Traceability in Healthcare Using GS1 Standards

Andrew Smith – St James's Hospital, Dublin, Ireland

Date: Thursday 8 October 2014

**Time**: 08:30 – 9:30 (U.S. East Coast)

13:30 - 14:30 (Ireland/UK)

14:30 – 15:30 (Euro Zone)

http://www.gs1.org/healthcare/hpac\_webinars