



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



Richard Price, Policy and Advocacy Officer, EAHP

po@eahp.eu

Outline of Presentation

- **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 2013 Leuven event**
- **Take home messages**
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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.

2. 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'unité commune de dispensation soit la plus proche possible de l'unité commune d'administration.

3. 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 ophthalmique, oto-rhino-laryngologique, vaginale, ...)
- formes dermatologiques liquides ou pâteuses.

4. Buts

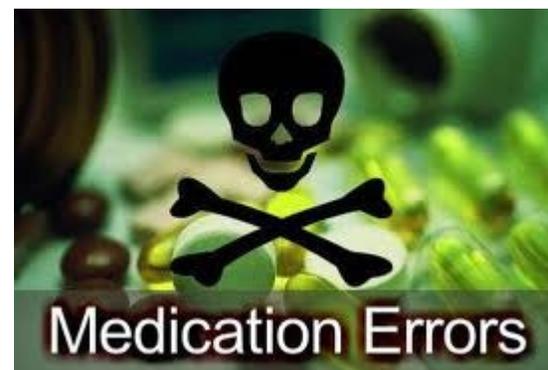
DELIVRER ET ADMINISTRER LE BON MEDICAMENT AU BON MALADE, PAR LA BONNE VOIE D'ADMINISTRATION AU BON MOMENT, AU BON DOSAGE.

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 **complete** identification of the medicine, **up to its point of administration**, 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 **7,000 due to medication error**
- Later, in 2006, IOM estimated medication errors cost **3,5 billion dollars** in the US, according to conservative estimation
- IOM has recommended **process automation** 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 **Federation of American Hospitals (FAH)** 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 **85%** from bedside bar code scanning
- A study conducted at a Veterans Affairs Medical Center of bar-code scanning systems, noted the system helped administer **5.7m doses of medication without medication errors.**
- FDA also estimate bar code rule will prevent nearly **500,000 adverse events** 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 frameworks should “*require complete and unambiguous labelling of **every single unit of use** of all licensed medicines products (e.g. tablet, vial & nebulas), including the INN, trade name, strength, expiry date, batch number and a data matrix bar code.*” **NOT YET ENACTED**



The other benefits of bar coding to the single unit

Assisting in the recall of medicines

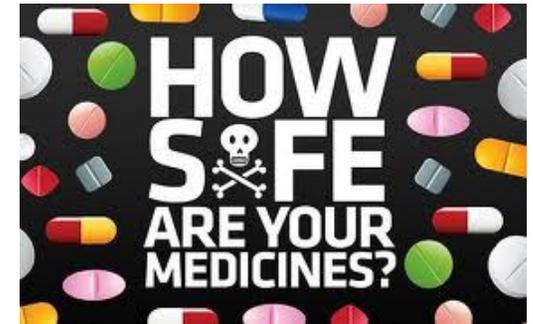
- Nature of medicines use in hospitals means that drugs which are dispensed in multiple blisters often have to be **cut, separated and spilled** out from their original blister package
- Without a bar code, information may be absent from the individual unit of medicine and an accurate control at the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



The other benefits of bar coding to the single unit

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.



The other benefits of bar coding to the single unit

Supporting comprehensive management of medicines information

- Accurate information about how medicines are used increasingly important in a cost-conscious 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



The other benefits of bar coding to the single unit

Preparing for an ageing society

- Large increase in elderly population, associated with **multi-morbidities** and **polypharmacy**
- **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



What obstacles?

- Europe is not the USA – the European political and regulatory landscape is more fragmented and political authority in the area of medicines remains largely a national competence
- Change is associated with some short terms costs
- Is Europe ready?



Working together as one

October 2014 Leuven event

- Patients, HCPs, industry & others examined evidence & discussed way forward
- Patient safety benefits of bedside scanning & desirability of single unit bar coding to facilitate recognised
- Wide partnership required – more than hospital pharmacy and industry
- High risk & high value meds 1st?
- Static v variable data recognised
- Issues still under consideration with EFPIA. News hoped soon.

A high level meeting on reducing medication error in hospitals:
Making bedside scanning a systematic reality across Europe.

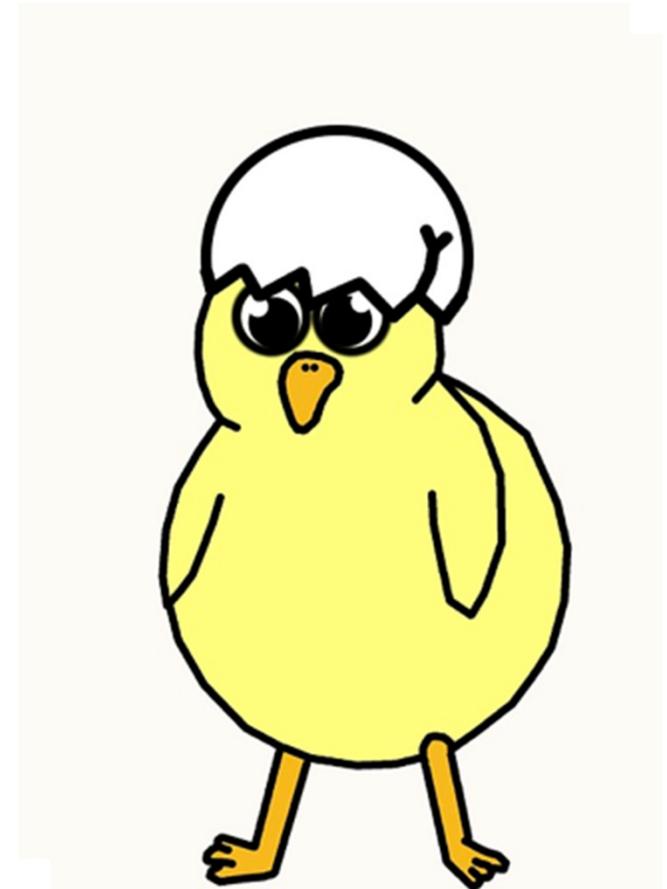


Monday 14th October 2013
UZ Leuven, Belgium

A REPORT OF PROCEEDINGS & CONCLUSIONS

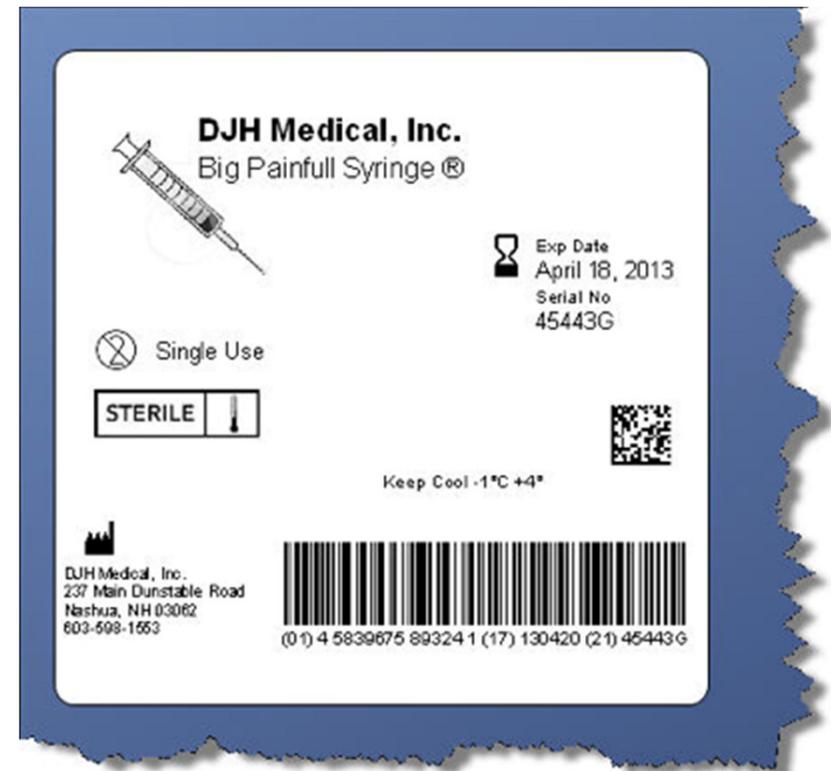
Falsified Medicines Directive: a start not an end

- 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

- For nearly 30 years patient safety in Europe has been held back by the failure to achieve systematic bar coding of medicines to the single unit
- However, a broad based coalition to help design and implement a timetable for achieving single unit bar coding exists and can be galvanised to action
- Other broader trends indicate the further need and wisdom of achieving this goal –such as our ageing society, the fight against counterfeit medicine, and the possibilities for patient use via mHealth.



**KEEP
CALM
AND
MAKE IT
HAPPEN**



Thank You!

Further information

Online: <http://www.eahp.eu>

Email: richard.price@eahp.eu

Telephone: 00 32 2 741 6835

