The Global Language of Business

Introduction to GS1 and GS1 Healthcare

Safer, more efficient care starts with a simple scan

Ulrike Kreysa, Senior Vice-President Healthcare, GS1 Global Office, Brussels/Belgium
21st January 2019

My background

- ✓ Studied pharmacy
- ✓ Worked 9 years in public pharmacies
- ✓ Worked 11 years in large university hospital
- ✓ Worked 3 years at data exchange provider
- ✓ Since 14 years at GS1
- ✓ Responsible globally for healthcare

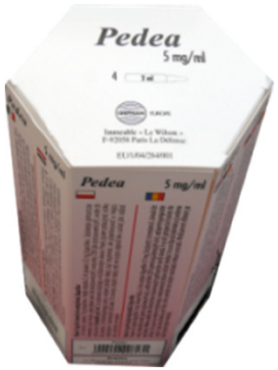
stand·ard [stan-derd]
noun
1. something considered by [...] general consent as a basis of comparison; an approved model.

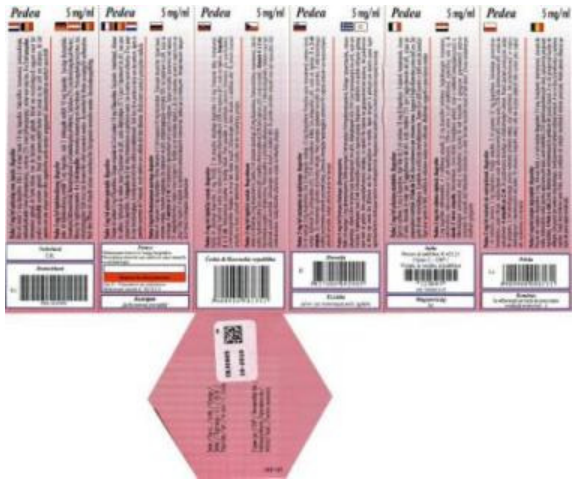
www.dictionary.com

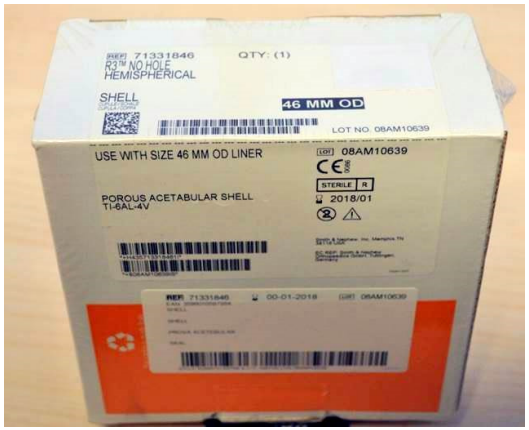
WHY?

Lack of standards in daily life is inefficient and annoying…

..in Healthcare it is dangerous and ineffecient!







- Multiple bar codes on one package – which one to scan?
- Different types of bar codes – **inconsistency; incompatibility**
- No bar code – need to bar code; re-package; re-label

The Need for Global standards in Healthcare

Diverging country requirements

Manufacturing headache

"CUSTOMIZED ACTIONS MEAN COSTS!!
Harmonisation of regulatory requirements and data standards will enable efficiency of a global product offering – otherwise complexity and cost will continue to raise"

Senior Executive, MD company

GS1 – a global standards organisation

1 million	150 countries	6 billion	112 MOs
over 1 million companies worldwide use GS1 standards	25 industries served across 150 countries	Barcodes scanned more than 6 billion times per day globally	112 Member Organisations around the world

GS1 is both global and local

GS1 Global Office

Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programmes...

GS1 Member Organisations

Local offices in 112 countries around the globe. Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...

Recognised NGO status by UN

UNITED NATIONS NATIONS UNIES

DEPARTMENT OF ECONOMIC AND SOCIAL AFFAIRS

Office for ECOSOC Support and Coordination – NGO Branch

DC1-1480, 1 UN PLAZA, NEW YORK, N.Y. 10017

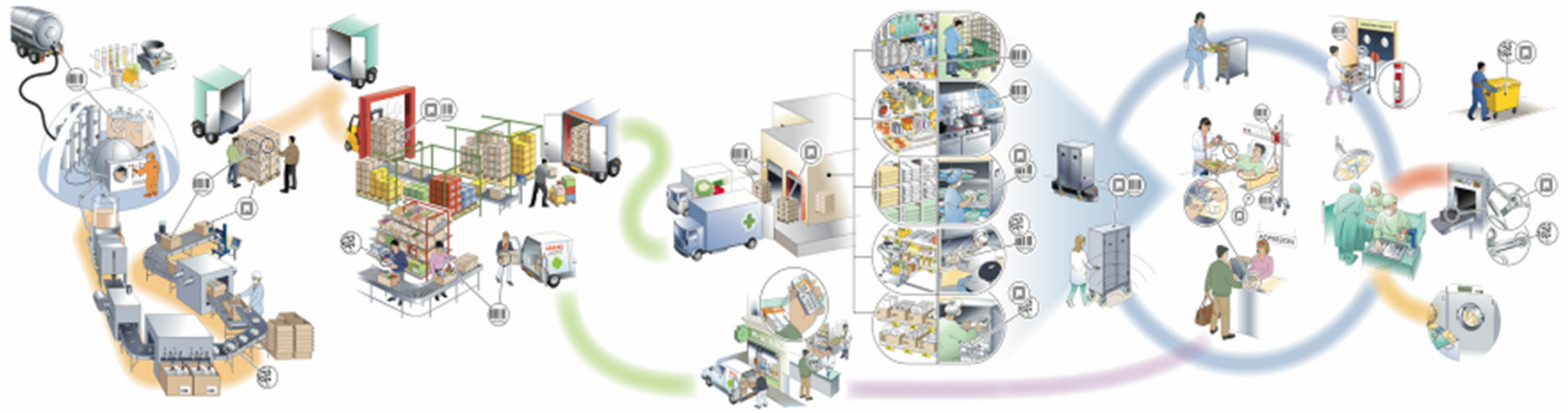
Tel: (212) 963-8652 • Fax: (212) 963-9248
www.un.org/ecosoc/ngo

1 August 2011

Dear NGO Representative,

I am pleased to inform you that the Economic and Social Council (ECOSOC) at its Substantive Session of July 2011 adopted the recommendation of the Committee on Non-Governmental Organizations (NGOs) to grant Special consultative status to your organization "GS1". On behalf of all staff of the Non-Governmental Organizations Branch, please accept our heartfelt congratulations.

Voluntary, Global Healthcare User Group



GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards enhancing **patient safety, operation** and **supply chain efficiencies**.

Our vision

GS1 Healthcare envisions a future in which the healthcare sector achieves **harmonised implementation** of **global standards** in **business and clinical processes** enabling **interoperability**, optimal **quality** and **efficiency** of healthcare delivery to **benefit patients**

patient safety

supply chain
security & efficiency

traceability

product data

GS1 Healthcare: an expanding, committed community of globally engaged stakeholders…

…and there are many more companies working with GS1 at a local level

Leading hospitals implement GS1

Working with global organisations…

International Organisation for Standardisation

European Committee for Standardization

Health Level 7 International

International Health Terminology SDO

Clinical Data Interchange Standards Consortium

Integrating the Healthcare Enterprise

Digital Imaging and Communications in Medicine

Joint Initiative Council

World Health Organization

World Customs Organization

International Hospital Federation

International Council for Commonality in Blood Banking Automation

International Society for Quality in Healthcare

European Association of Hospital Pharmacists

European Federation of Pharmaceutical Industries and Associations

European Medical Devices Industry Association

User-driven:
GS1 Healthcare LT 2018/2019

Tri-Chairs:

- Scott Mooney, McKesson
- Feargal Mc Groarty, St. James's Hospital
- Mark Hoyle, Teleflex

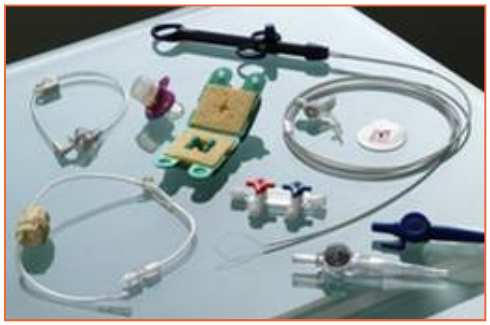
LT Members:

- Charity Hovey, 3M
- Cyndi Poetker, Abbott
- Jeff Denton, Amerisourcebergen
- Volker Zeinar, B. Braun
- Stefan Artlich, Bayer
- Dennis Black, BD
- Patrick Main, Cook Medical
- Kevin Downs, University Hospitals of Derby and Burton NHS Foundation Trust
- Mike Meakin, DHL
- Sébastien Langlois-Berthelot, F. Hoffmann-La Roche
- Karen Conway, GHX
- Grant Courtney, GSK
- Jean-Michel Descoutures, IHF
- Gerry Collins, Johnson & Johnson
- Jackie Elkin, Medtronic
- Pascal Aulagnet, Pfizer
- Grant Hodgkins, Smith & Nephew
- Dr. Hajo Reissmann, University Medical Center Schleswig-Holstein
- Catherine Koetz, GS1 Australia
- Marcelo Oliviera, GS1 Brazil
- Arthur Smith, GS1 Canada
- Valérie Marchand, GS1 France
- Hans Lunenborg, GS1 Netherlands
- Rami Habbal, GS1 UAE
- Glen Hodgson, GS1 UK
- Siobhan O'Bara, GS1 US


Health
costs


One of these medicines is fake.
Can you tell which?
RECALL

The healthcare supply chain needs global standards



- Medication errors result in additional treatments, disabilities and even loss of life
- Counterfeiting is an increasing global threat
- Traceability from manufacturer to patient is problematic
- Product recalls can be difficult to manage, in particular for healthcare providers
- Manual interventions in the healthcare supply chain decrease its efficiency and accuracy

The Healthcare Supply Chain

Medication Errors – happening today

US

- 44,000-98,000 die in the US alone as the result of medication errors *(IoM, 2006)*
- More than Motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516)
- Estimates of cost for US figures- $17-$29 Billion annually $2,000- $5,000 ent (HDMA, 2004)

UK

- Approximately 10% of inpatient episodes result in a m
- Of the 8 million hospital admissions in England afety incident, Costing the National Health Service £3

New Zealand

- In hospital adverse se are preventable) 5,000 patients experience an abled

Germany

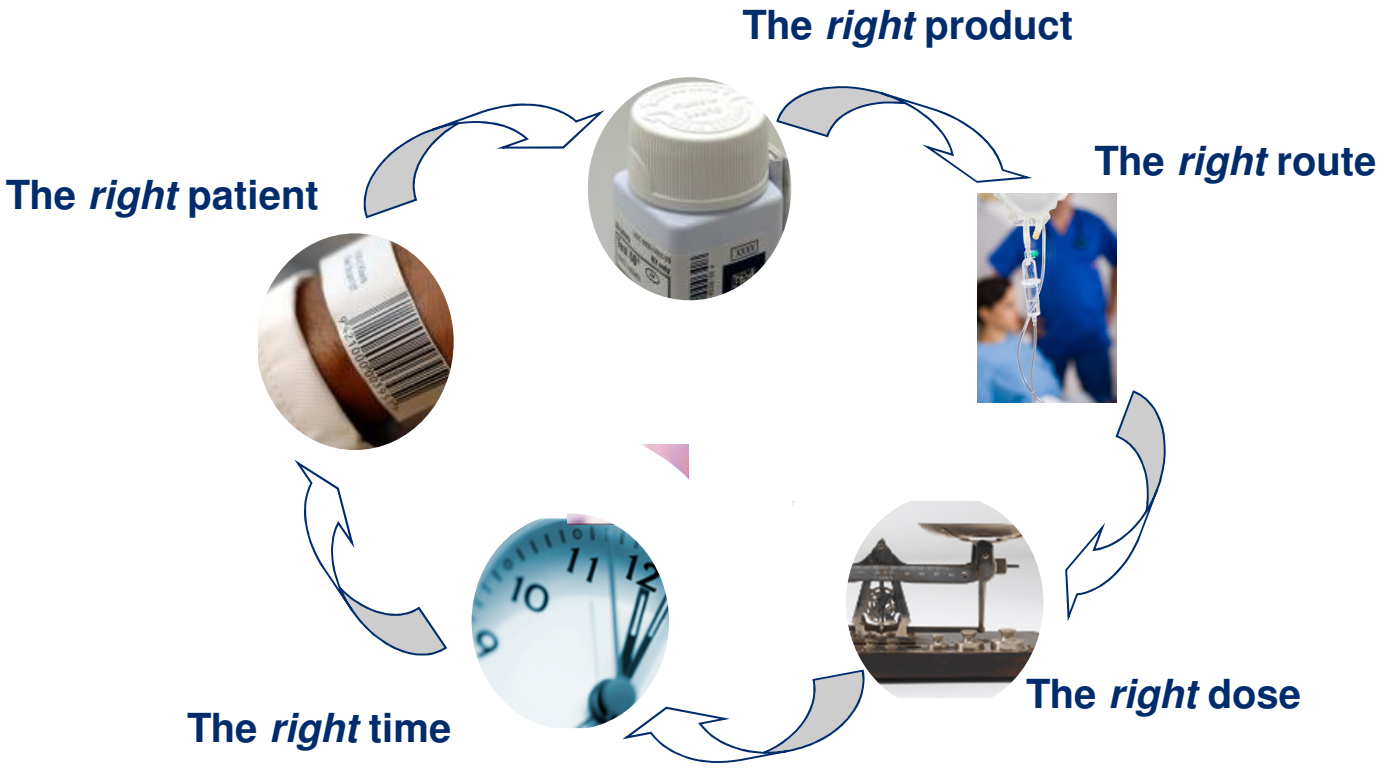
- "17,000 die fro tsches Arzteblatt International, March 5, 2010)

East Africa

- "Medical error is pensive for life" (In2EastAfrica, January 22, 2012)

Globally this is the equivalent of a Jumbo Jet falling out of the sky every day with 100% fatalities

Ensuring the '*5 Patient Rights*'



Benefits for Patient Safety

- Improved recall procedure and adverse event reporting
- Documentation of product/patient relationship – in electronic health records (EHR) and registries
- Visibility of inventory – availability of devices
- Reduction of medical errors
- Supply chain security/anti-counterfeiting

Why regulation? A main driver - counterfeiting

According to Interpol more than **one million people** die each year from counterfeit drugs!

An estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified. They affect every region of the world.

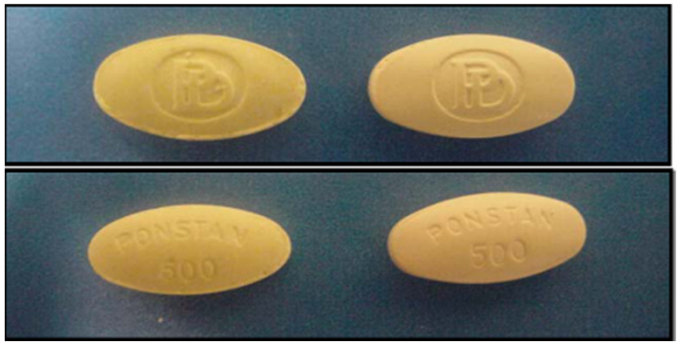
WHO Fact Sheet on Substandard and Falsified Medical products, 31 January 2018

The Need for Global Standards in Healthcare

Lack of transparency in the Healthcare supply chain, making it **vulnerable to infiltration** by counterfeiters.

Healthcare Scenario – Pharmaceutical Counterfeits

Could you tell the difference?



- One of these tablets is counterfeit and the other one is genuine
- Counterfeit tablets may have:
- no active pharmaceutical ingredient (API) or
- a dangerous coating, e.g. lead-containing paint or floor wax
- OR worse…

Healthcare Scenario – Crisis and Impact: counterfeit cancer treatment in the legitimate US distribution

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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Drugs

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- Medication Guides
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- Drug Shortages
- Postmarket Drug Safety Information for Patients and Providers
- Information by Drug Class
- Medication Errors
- FDA Drug Safety Newsletter
- Drug Safety Podcasts
- Safe Use Initiative
- Drug Recalls
- Drug Integrity and Supply Chain Security

Counterfeit Version of Avastin in U.S. Distribution

Statement Issued: Feb. 14, 2012

FDA sends letters to 19 medical practices about counterfeit product and other unapproved cancer medicines

The U.S. Food and Drug Administration (FDA) is warning health care professionals and patients about a counterfeit version of Avastin 400mg/16mL, which may have been purchased and used by some medical practices in the United States. Avastin is an injectable medicine used to treat cancer and is administered to patients in clinics, hospitals, and doctors' offices. The counterfeit version of Avastin does not contain the medicine's active ingredient, bevacizumab, which may have resulted in patients not receiving needed therapy.

In a related action, FDA has issued letters to 19 medical practices in the United States that purchased unapproved cancer medicines that may include the counterfeit Avastin. The counterfeit version is labeled as Avastin, manufactured by Roche. Roche is the company that manufactures Avastin approved for marketing outside of the United States.

Roche conducted laboratory tests that confirmed the counterfeit version of Avastin. Packages or vials may be counterfeit if they:

- are labeled with Roche as the manufacturer
- display batch numbers that start with B6010, B6011 or B86017

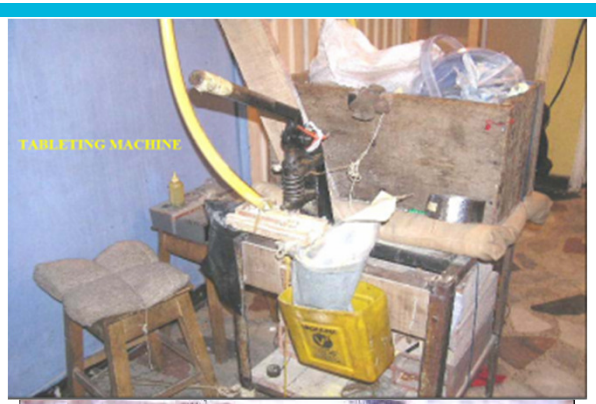
The only FDA-approved version of Avastin for use in the United States is marketed by Genentech (a member company of Roche). The FDA-approved version does not include the Roche logo on the packaging or vials. In addition, Genentech's FDA-approved version of Avastin vials and packaging have a 6-digit numeric batch number and expiration dates in a 3-letter month and 4-digit year format (e.g., JAN 2014). Genentech's Avastin products are safe and effective for their intended uses.

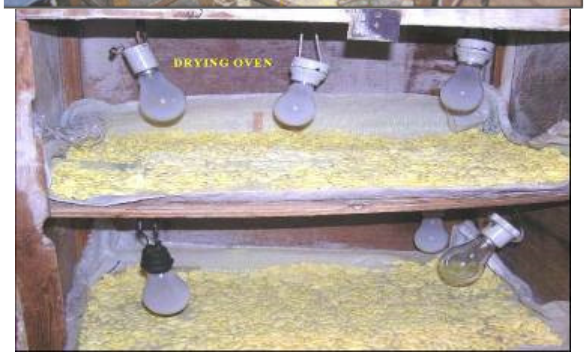
The 19 medical practices in the United States purchased unapproved cancer medicines and, potentially, the counterfeit Avastin, from Quality Specialty Products (QSP), a foreign supplier that may also be known as Montana Health Care Solutions. Volunteer Distribution in Gainesboro, Tennessee is a distributor of QSP's products. FDA has requested that the medical practices stop using any remaining products from these suppliers. FDA cannot ensure the safety or efficacy of any of these unapproved products.

Is Europe safe?

In 2018: Parallel import companies have discovered four falsified batches of cancer medication, Velcade, in the Dutch and Danish supply chain

Healthcare Scenario – Pharmaceutical Counterfeits





A counterfeit medicines "factory"

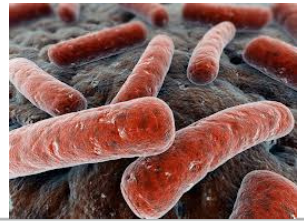
- The Pharmaceutical industry deals with the most frequently counterfeited products worldwide.
- This is a manufacturing process: the tableting machine and drying process belong to a criminal gang of **counterfeiters.**
- Where's the traceability, GMP*, safety, lot management?

** Good manufacturing practices*

But also substandard drugs are a danger for patient safety

Tuberculosis

- 8 million people get sick every year, in 2011 1,4 million died from it
- Recently research team collected samples of two commonly used medicines, isoniazid and rifampicin, from neighborhood pharmacies and markets in 17 countries where tuberculosis is pervasive
- Nearly **one of every 10 pills** failed to meet basic quality standards. In African countries, **one in six pills** was substandard.
- Consequences: People die - resistance is developing, which could be a global threat



Source: Roger Bates in New York Times 5 Febr. 2013

Another example of substandard medicines

- Substandard diphtheria, pertussis, and tetanus (DPT) vaccines in China caused major concern in the public in 2018
- Requests for a better controlled system
- Draft regulation for traceability
- Recently expired vaccines were used

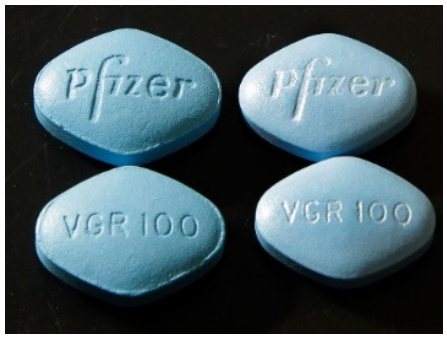
The economic impact

European study on the economic impact of counterfeit medicines in the European Union marketplace and its wider costs to industry, government and society shows.

- **Main findings:**
- 4.4 % of sales lost annually by the sector due to counterfeiting
- EUR 10.2 billion of revenue lost annually by the sector
- Additional EUR 7.1 billion of revenue lost annually in related sectors
- 37 700 direct jobs lost annually
- 90 900 direct and indirect jobs lost annually
- EUR 1.7 billion of government revenue lost annually (taxes and social contributions).

Source: EU IPO (Intellectual Property Office), September 2016

https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/resources/research-and-studies/ip_infringement/study9/pharmaceutical_sector_en.pdf



Combating counterfeiting

The introduction of a unique identification for drugs or medical devices, where appropriate, will enable **authentication and traceability systems**

This will **make it much more difficult** for counterfeiters to intrude into the Healthcare supply chain

GS1 standards play a major role !

Multiple standards put benefits at risk

Higher costs

Higher risks

Slower adoption

The need for global standards

Healthcare is **local**

- Healthcare providers are local
- Regulations are local

Healthcare is **global**

- Healthcare supply chains often cross borders

Country-by-country solutions are not sufficient nor effective

A global harmonised approach and implementation is needed

New McKinsey & Company report quantifies supply chain issues in Healthcare

Source:
http://www.mckinsey.com

New McKinsey report "**Strength in unity: The promise of global standards in healthcare**"

Highlights the **cost savings and patient safety** benefits of adopting a **single global supply chain standard in healthcare**

Available at:
http://www.gs1.org/healthcare/mckinsey

McKinsey did extensive research to quantify the business case for global standards and to define a roadmap for adoption

Objective

- Step change for global standards awareness amongst key healthcare stakeholders in all the countries by publishing a research report explaining and quantifying the benefits of global standards and services for the healthcare industry

Description of our research

- Reviewed existing case studies and relevant literature
- Interviewed ~80 top healthcare executives along the value chain in 15 countries
- Used McKinsey proprietary databases and benchmarks, and various experts
- Developed business cases including cost and benefit of global standards
- Defined a high-level industry adoption roadmap

Huge cost savings and patient safety benefits when adopting a single global standard in healthcare

"Implementing **global standards** across the entire healthcare supply chain **could save 22,000-43,000 lives** and avert 0.7 million to 1.4 million patient disabilities"

"Rolling out such standards-based systems globally **could prevent tens of millions of dollars' worth of counterfeit drugs** from entering the legitimate supply chain"

[We] "estimate that **healthcare cost could be reduced by $40 billion-$100 billion globally**" from the implementation of global standards

"Adopting **a single set of global standards** will cost significantly less than two" (between 10-25% less cost to stakeholders)

SOURCE: McKinsey report, "Strength in unity: The promise of global standards in healthcare", October 2012

Developments across the world

Regulatory bodies need to address Public Health

Hospitals and global organisations look for improvement in patient care and cost reduction

This is a global development…

Be prepared, informed, ready for regulatory requirements and your customers

My very personal reasons to care about patient safety…

...and the highest quality of care.