The Global Language of Business

# GS1 Healthcare Newsletter

**Special feature:**
GS1 Healthcare Conference in Copenhagen

N°30
2015

## Content



## Copenhagen welcomes the biggest global GS1 Healthcare Conference yet!

The latest global conference which took place in Copenhagen in October 2014 was the biggest in its history, with over 350 participants from 43 countries, a record breaking number. This continues to prove the strong interest in improving patient safety and supply chain efficiencies with global standards.

*"All Danish hospitals in the future will have to use GS1 standards."*

Mr. Nick Hækkerup, Danish Minister of Health

Mr. Nick Hækkerup, Danish Minister of Health, strongly gave his support to GS1 standards in his key address. He covered the challenges industry is facing and how GS1 standards are helping healthcare professionals move the supply chain to provide safer patient care and more transparent processes.


He made a ground breaking statement that all Danish hospitals will all have to implement GS1 standards.

During the three days of the conference, diverse topics were covered. Participants had the opportunity to learn about GS1 implementations in hospitals, the latest updates on regulations from authorities and governments on unique device identification and drug serialisation, and the potential use of GS1 standards to improve the vaccines supply chain.

Participants attended for the first time a poster session cocktail. Twelve posters were presented which demonstrated local implementation of GS1 Healthcare standards.

Last but not least, GS1 supported the Danish charity, the Danske Hospitals Klove (Danish Hospital Clowns). For each survey completed, GS1 donated 5€ to the charity and managed to collect 1.500€ thanks to the high participation of our attendees. Thank you to everyone who contributed!

**For more information, download the conference presentation.**

## THE CONFERENCE IN NUMBERS

**350** attendees from
**43** countries
**28** plenary speakers
**14** panellists
**12** posters
**6** site visits
**5** breakout sessions
**3** ask the expert sessions
**2** working lunches
**1** successful conference!

# Hospital implementations

## The new NHS eProcurement strategy in the UK


Lord Philip Hunt, UK Shadow spokesperson, President of the Healthcare Supply Association and President of the Royal Society of Public Health, spoke about the latest developments relating to England's National Health Services (NHS) eProcurement strategy, in which GS1 standards are mandated. The Department of Health's new eProcurement strategy is an important element of a wide programme of work expected to deliver between £1.5 and £2 billion of savings by the end of 2016.

The strategy, as explained by Lord Philip Hunt at the conference, is built in two stages:

- **Short term:**
  - Develop a proposition to help NHS trusts deliver £1.5-2bn savings
  - Increase transparency
- **Medium/long term:**
  - Create a new national 'enabling' function (NHS Centre of Procurement Efficiency)
  - Home of professional development, data, analytics, diagnostics, benchmarking, best practice and networking
  - Implement an eProcurement strategy following GS1 standards.

**For more information, download the conference presentation.**

Following Lord Hunt's presentation, Andrew McMinn, Plymouth Hospital, presented the positive impact the eProcurement strategy will have for his hospital: "Patient care is directly affected by the success or failure of procurement processes". He also agreed with the results of the McKinsey report, "Strength in Unity" which indicates recurring annual savings of £3m-£5m for a 600 bed acute NHS provider with the application of GS1 standards to hospital procurement activity.

**For more information, download the conference presentation.**

# Denmark implementing GS1 standards for its healthcare system

We had the honour of welcoming different stakeholders of the Danish healthcare supply chain who presented the benefits GS1 standards bring for their healthcare system.

Gitte Bengtsson, from the Danish Regions, representing the interest of Danemark's five regions, gave an overview on the implementation of GS1 standards in a Danish setting and presented how GS1 standards improve patient safety and treatment efficiency in Danish hospitals: "By choosing GS1 standards, we quickly realised that it can generate many positive effects regarding patient safety, safety in workflow for staff and has many economic benefits as well. By choosing one standard across the country, we achieve a higher level of safety for our patients."

Gitte insisted that organisations should not choose between quality and efficiency, but aim for both. She then added "The regions' choice of implementing GS1 standards was obvious as it is the most international widespread standard within the healthcare system. Our suppliers have therefore started to use GS1."

The Danish Regions have established a group consisting of Healthcare CEOs and Regional CEOs, who manage the implementation of global standards in the regions. She concluded that the region's next step is to ensure that global standards are implemented across the entire supply chain and in their healthcare system and hospitals.

*"By choosing one standard across the country, we achieve a higher level of safety for our patients"*

*Gitte Bengtsson, Danish Regions*

Amgros, a drug procurement organisation, ensures effective supply and safe use of medicine to patients to the majority of hospitals in Denmark (99.5%). Amgros focuses on getting discounts by making tender and framework agreements, and controlling the supply chain.

With up to 17.000 hospitalisations affected by medication errors in Denmark, Amgros has decided to implement GS1 standards to take action.

*"17.000 hospitalisations affected by medication errors in Denmark"*

*Flemming Sonne, Amgros*

Since 2011, Amgros demands in their tender agreements that primary packages be barcoded with GS1 standards using EAN-13 or GS1 DataMatrix. This means that all drugs can be scanned and encoded which complies with the five patient rights: the right patient, the right drug, at the right dose, via the right route, and at the right time.

Mr Sonne emphasised that many benefits arise from barcoding such as improved patient safety due to less medication errors, reduced adverse drug events, and better stock and logistic management.

The last Danish speaker, Viggo Nielsen, represented the Hospital Pharmacy of the Capital Region, one of the largest hospital pharmacies in the northern part of Europe. The Hospital Pharmacy of the Capital Region chose to work with GS1 standards.

Finally, Mr Nielsen, concluded his presentation by stating that implementing GS1 standards is easier than some might think!

**For more information, download the conference presentations: Reducing medication errors in Danish hospitals with primary package barcoding, Flemming Sonne, AMGROS**

**How GS1 barcodes improve logistics quality and patient safety, Viggo Nielsen, Hospital Pharmacy Capital Region**

# GS1 presents the HPAC awards

Early in 2013, the GS1 Healthcare Provider Advisory Council (HPAC), composed of hospital and pharmacy experts, introduced two awards:

• The Provider Recognition Award, for an individual, at a hospital or pharmacy, who has contributed highly to the GS1 Healthcare work efforts over the years.

• The Provider Implementation Best Case Study Award, for provider organisations or individuals who have implemented GS1 standards for at least one process in their healthcare department or provider (e.g., hospital, clinic, care home, pharmacy) with clear and demonstrable return on investment.

**left to right: Richard Price (EAHP), Jan Somers (GS1 Belgium & Luxembourg), Xavier Lemaitre (UZ Leuven), Thomas De Rijdt (UZ Leuven), Severine Dewerpe (GS1 Belgium & Luxembourg)**

These awards were presented at the Global GS1 Healthcare Conference in Copenhagen to two exceptional contributors.

**Thomas De Rijdt,** assistant-head of pharmacy UZ Leuven, received the Provider Recognition Award for his long-standing involvement in the promotion and implementation of GS1 standards. He has made "unparalleled" contributions to the implementation of the GS1 standards in the Belgian healthcare provider sector. His project on bedside scanning and identification of pharmaceutical product to the level-below-each, has dominated the development of new hospital IT-systems and ensures that the five patient rights are well implemented in his hospital.

He established a new way of identifying medication and patients using GS1 barcodes. As a result, less medical and prescription errors occur and nurses are in a position to better manage patients' treatment.

**Bernhoven Hospital**, represented by Justin Bitter and Erik van Ark, received the Provider Implementation Case Study Award.

This case study highlights the benefits of GS1 standards to achieve full visibility in the process flow of medical devices used with patients in the operating room. Bernhoven Hospital implemented GS1 product identification (GTIN) and Global Location Numbers (GLN). The objective was to carry out efficient recalls when needed, and ensure accurate registration of implants in the electronic health record. This has helped Bernhoven Hospital to clearly improve the safety of their patients as the hospital is able of identifying which patients received what implants in case of recalls. It also quickly allows the hospital to reduce their stock level as they have a better vision of their inventory.

**Left to right, Pieter Maarleveld (GS1 Netherlands), Justin Bitter (Bernhoven Hospital), Erik van Ark (Bernhoven Hospital), Hans Lunenborg (GS1 Netherlands), Esther Peelen (GS1 Netherlands)**

Congratulations to Mr Thomas De Rijdt , Justin Bitter and Erik van Ark on their well-deserved awards!

**Submit your case study or your candidature for the next awards by contacting janice.kite@gs1.org**

# Unique Device Identification around the world

## Status of the IMDRF and the European Commission

Laurent Sellès, EU Commission, opened the plenary on Unique Device Identification (UDI) by presenting the status of UDI in the International Medical Device Regulators Forum (IMDRF). The focus is to create harmonised data sets for UDI databases. The new data fields and data sets will provide clear standardised rules on rights to access, read, write or correct data. The benefits expected will be:

- For the IMDRF "Regulators": future international alignment.
- For Industry: less burdensome UDI data base entries

Laurent Sellès then shared the UDI status in the European Union. He presented how UDI will interact with other parts of the EUDAMED database like Registration, Vigilance and Market Surveillance.

Laurent concluded by sharing that the adoption of the new regulations might be by end 2015 and that preparation of the delegated acts (UDI and traceability requirements) should be planned by end 2015 – beginning 2016.

**For more information, download the conference presentation.**

## A critical stage in the development of EU legislation on UDI

Mike Kreuzer took the stage to present the work done by the medical device industry in Europe, within Eucomed, on UDI and in particular the UDI database.

Eucomed welcomes and supports the creation of a UDI database aligned with the IMDRF global framework, which aims to address patient safety, traceability and transparency, but pointed out that a global harmonised system is essential.

**For more information, download the conference presentation.**

## Past the first U.S. FDA UDI deadline

Jay Crowley, former U.S. FDA Senior Patient Safety Advisor, presented the key learnings of the first implementation deadline of the U.S. regulation.

The U.S. FDA UDI rule can be complex to implement due to internal reasons (companies having grown through acquisition, additional label changes…). Jay Crowley recommends organisations that start complying with the UDI rule, to answer four main questions:

1. What does the organisation produce – product portfolio, its risk class…?

2. Who is the labeller?

3. How does the organisation label/package the medical device?

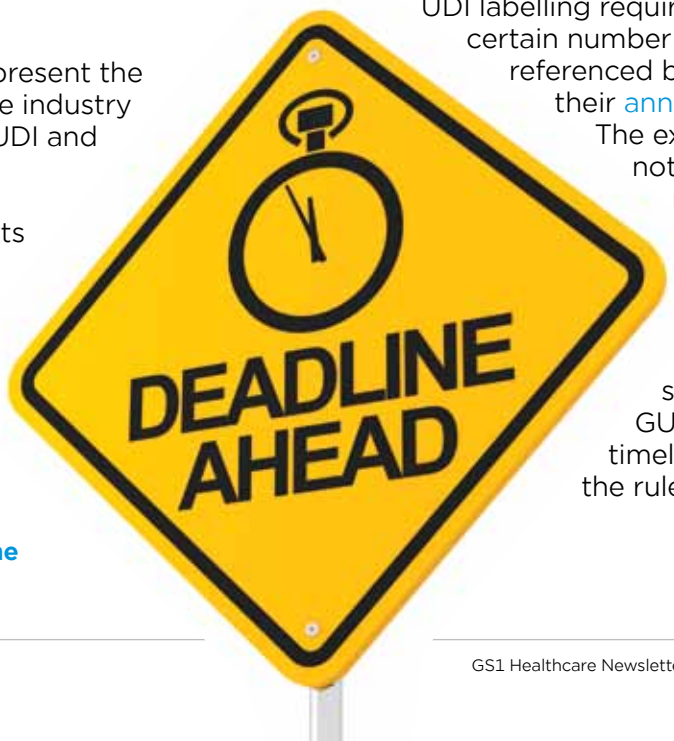
4. How can the organisation comply with the rule?

Jay also explained the differences between the U.S. FDA UDI rule and the IMDRF UDI proposition.

**For more information, download the conference presentation.**

## U.S. FDA extended deadline for the implementation of marking of some implants

The U.S. FDA has just announced that they give manufacturers who commercialise product in an unpackaged, non-sterile configuration, an additional year to develop the solutions to comply with the UDI labelling requirements for a certain number of products referenced by pro codes in their announcements. The extension does not include the requirement to submit data to the GUDID for these products, the data must be submitted to the GUDID within the timelines set out by the rule.



## Australia's healthcare supply chain reform

Kate Ebrill, Head of National Services Operation at the National E-Health Transition Authority (NEHTA), presented the latest updates on the Australian Supply Chain reform. NEHTA facilitated the development of a National Product Catalogue (NPC) which provides suppliers with a single mechanism to communicate structured catalogue data to many health customers. It also enables synchronisation of product and pricing data used for electronic procurement. The NPC is part of the GS1 Australia GS1net solution, a GDSN compliant datapool, and is the key to standardised data using GS1 Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs). The NPC implementation is growing fast: in September 2014, there were already 336,418 GTINs on the NPC, from over 464 participating organisations. NPC data has been integrated by other australian states with work underway towards full integration in South Australia and the Northern Territory.

Furthermore, progress has also been made following the launch last April, of GS1 Recallnet, an electronic product recall notification management system for therapeutic goods. Following Queensland and Victoria, other Australian states are planning GS1 Recallnet implementation. At the time of her presentation 70 supplier entities had subscribed to the system. Kate Ebrill shared the staggering results demonstrating the success of the new system: recent statistics showed recalls are actioned in between 53 minutes and 15 hours post–notification, whereas paper notifications could take up to 4-6 weeks.

**For more information, download the conference presentation.**

## Impacts of global standards in the Portuguese healthcare value chain

Professor Augusto Mateus from the Consulting Firm Augusto Mateus & Asociados presented the study "Impactos da adoção de standards globais na cadeia de valor da saúde em Portugal" which analysed the impact of the adoption of global standards in the Portuguese Healthcare value chain. Their study was based on the McKinsey report "Strength in unity: The promise of global standards in healthcare", and estimated that the potential savings for the Portuguese healthcare industry in the next 10 years could be from €561 Million to €791 million when implementing global standards.

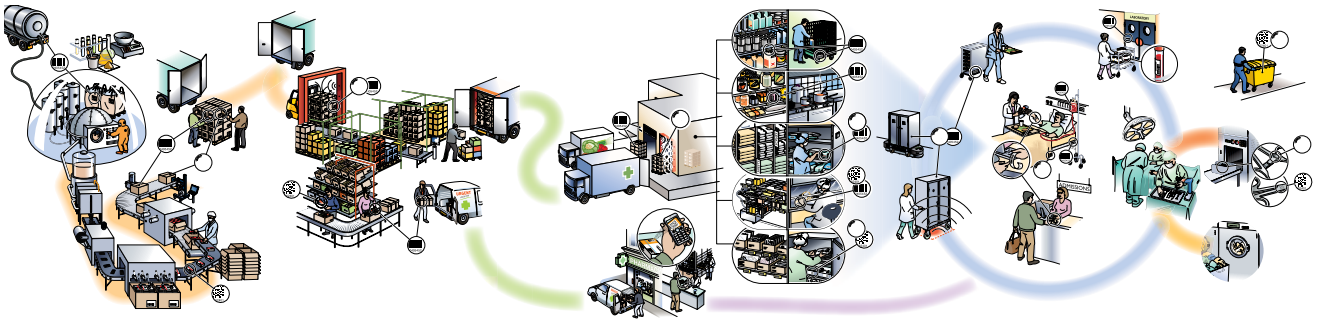
*"The potential savings for the Portuguese healthcare industry in 10 years would be up to €791 million"*

*Professor Augusto Mateus, Augusto Mateus & Asociados*

The study also estimated that hospitals could save on average €4.4 million by adopting global standards. In addition pharmacies could obtain accumulated potential savings of €129 million, followed by wholesalers, €99 million, the pharmaceutical industry, €68 million, and the medical device industry, €60 million.

Augusto Mateus added that the adoption of standards would allow greater efficiency and sustainability for the sector and would help fight against falsification and counterfeiting of medicines. Finally, Professor Mateus advised the participants that global standards ought to be adopted by focusing first on the implementation of GS1 barcodes containing a Global Trade Item Number, batch number and expiration date on all healthcare products; then in a second phase, implementing serialisation.

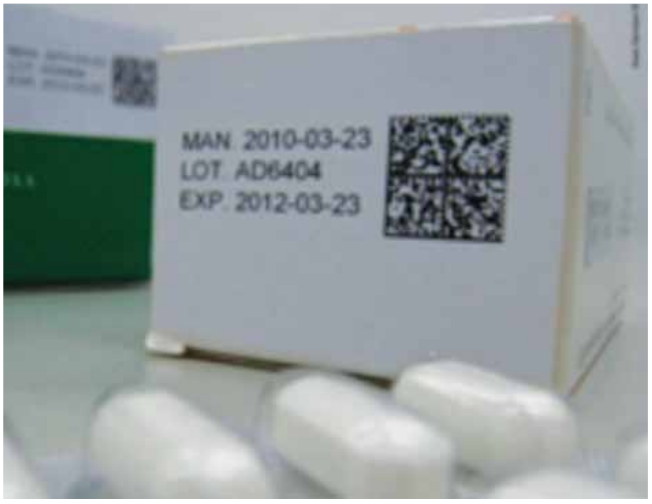
**For more information, download the conference presentation.**



Major Supply Chain Processes (http://www.gs1.org/docs/patient_safety/GS1_Standards_in_Healthcare.pdf)

# Traceability and the need to deliver the right product to the right patient

The final day of the conference was dedicated to the importance of traceability, which is today a focus of many regulatory bodies, with world-wide regulations and activities evolving. Speakers discussed traceability and authentication, counterfeiting and the need to get the right product to the right patient. Angeline Riezebos representing Sanquin, a Dutch organisation involved in the entire blood supply chain – from donor to patient –, shared how the company ensures traceability of product from beginning to end: since 2002, Sanquin is using GS1 identifiers and barcodes on all products.




## Key requirements of the EU Falsified Medicines Directive

For Christoph Krähenbühl from 3C Integrity, one of the key objective of the EU Falsified Medicines Directive (FMD) is to ensure product integrity and authentication of medicines (safety features and product serialisation). The publication of the Safety Features Delegated Act is expected to be released at the end of 2015. Christoph Krähenbühl strongly recommended to start acting now as the pace of adoption can be long. To do so effectively he advised the audience to engage with their senior stakeholders, and to seek the support of GS1 as the "coding" specialist.

**For more information, download the conference presentation.**

## European Stakeholder Model (ESM) verification of medicinal products in Europe

Mike Rose, representing EFPIA, shared the update on the European Stakeholder Model (ESM), a partnership of major EU associations representing the different stakeholders in the supply chain which aim is to comply with the EU Falsified Medicine Directive.

The principle of the ESM approach is that each pack of medicine is checked against a database before it is dispensed to the patient, ensuring that the patient receives a genuine and safe product. This is achieved through the use of two-dimensional barcodes containing the product identification (e.g. Global Trade Item Number, expiration date, batch / lot number and serial number). By simply scanning the barcode, any unregistered or duplicated code will immediately alert the pharmacist about the possibility of a falsified product.

The European Hub, managed by the European Medicines Verification Organisation (EMVO), will enable the connection to national hubs and/or healthcare manufacturers from January 2015 onwards.

**For more information, download the conference presentation.**

## Mass serialisation and traceability

Mathieu Aman, from F. Hoffmann-La Roche, shared his company's vision on barcodes, serialisation and traceability. "Applying a 2D Barcode on packs is just the beginning of the journey and it's not only about traceability" said Mathieu Aman. The importance of packaging is increasing in the pharmaceuticals industry as there is an ongoing focus towards more control and security in todays' global pharmaceutical supply chains. Using GS1 standards has enabled Roche to apply some strategic thinking by focusing on a global solution that answers different local needs. He made a point stating that adding a GS1 DataMatrix on packaging would be an accelerator towards e-health or mobile-health, presenting a great opportunity for a new kind of healthcare innovation such as:

- Digitisation of supply chains with efficiency increase
- Interaction with payers e.g. by supporting value-based pricing models

- New electronic/mobile patient behaviours e.g. mobile computing authentication, e-leaflets
- Paperless transactions e.g. prescription, reimbursement and dispensing
- New type of scanning-based customer services
- New practices arising from «personalised medicine»

**For more information, download the conference presentation.**

## How to comply with the U.S. Drug Supply Chain Security Act Rule using GS1 standards

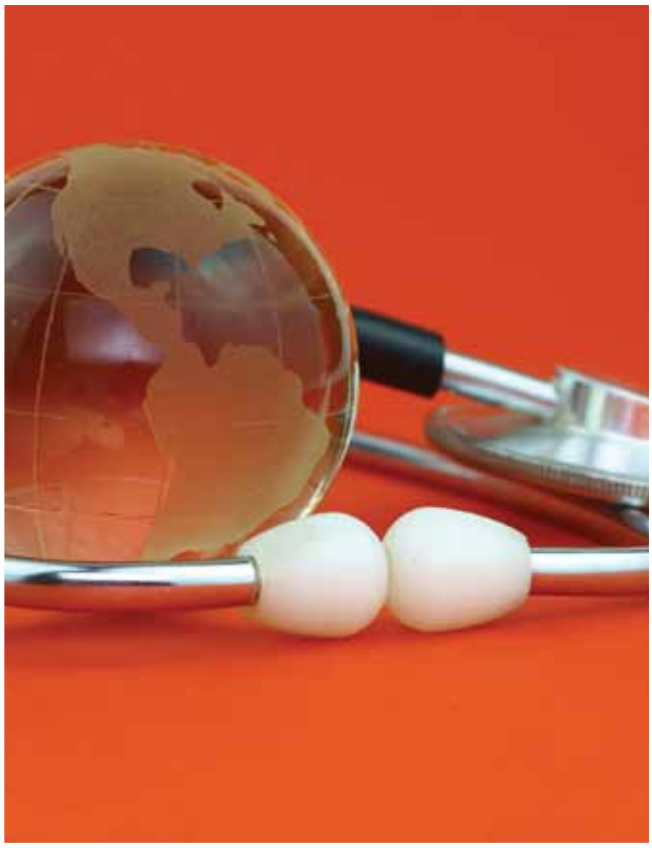
Chris Reed, Johnson & Johnson, explained to the audience how GS1 standards can help to comply with the new Drug Quality and Security Act (DQSA), designed to secure the pharmaceutical supply chain. The DQSA adopted in November 2013, gives the U.S. Food and Drug Administration (FDA) a national system for tracking prescription medicines from manufacturer to pharmacy.

The requirements will be phased in over a period of 10 years by providing a migratory path from lot-based traceability to serialisation and then item-level traceability.

He advised the audience to use EPCIS, to implement the requirement.

**To find out more about EPCIS, download our brochure or download our EPC Information Services (EPCIS) standard**

**For more information, download the conference presentation.**



## The road from Nordic Trade Items to Global Trade Item Numbers

In February 2014, LIF (Swedish Association of Pharmaceutical Manufacturers) recommended pharmaceutical manufacturers and supply chain partners in Sweden to transition from a national code to the globally harmonised GS1 Global Trade Item Number (GTIN). At the conference in Copenhagen Hans Andersson from LIF presented their journey. LIF agreed that uniquely identifying healthcare items is crucial from a patient safety perspective. With globalisation, the Swedish pharmaceutical market changed, therefore their national numbering system was no longer suitable for identifying each item.

The full implementation of GTIN on all pharmaceutical drugs in Sweden is expected to be completed by 2018.

This recommendation should positively influence the other Nordic countries toward a move to GTIN for the identification of drugs.

**For more information, download the conference presentation.**

The VPPAG recommends the following guidelines for vaccine product labels:

• Include barcodes on all packaging levels used by manufacturers, with the exception of the primary packaging level, conforming to GS1 standards and associated specifications

• Barcode data should include the Global Trade Item Number (GTIN), lot number, and expiration date

**For more information, download the conference presentation.**

## UNICEF implement barcoding for an improved supply chain

Prakash Vaidyanathan from UNICEF presented how the organisation implemented barcodes to improve their supply chain management.

Barcodes have been used in the UNICEF supply division warehouse at Copenhagen for over 15 years. Today, UNICEF wishes to expand the use of barcodes to other country offices, using GS1 standards.

UNICEF is now considering to indicate barcodes as a preferred characteristic for vaccine supplies in future tenders.

**For more information, download the conference presentation.**

# Improving the vaccines supply chain

The closing plenary focused on the vaccines supply chain with speakers from Pfizer, UNICEF and PATH.

## WHO VPPAG recommends GS1 standards for vaccines

Rich Hollander, from Pfizer, presented the World Health Organisation (WHO) Vaccine Presentation and Packaging Advisory Group (VPPAG) and its barcode subgroup, in his compelling presentation. The Vaccine Presentation and Packaging Advisory Group (VPPAG) is a forum for reaching consensus on vaccine product attributes. It was created in order to enable better access of vaccines to children in need, in developing countries, by improving the visibility in the supply chain. Established in 2007 by the GAVI Alliance, VPPAG is now convened by UNICEF and WHO.

"What if.....in five years, any country, multilateral organisation, and donor in the world can track the movement of vaccines from manufacturer to recipient through the use of inexpensive, easily usable, and reliable barcode technology?"

**Dr. Henry Mwanyika, PATH**


## Tanzania leading the way with barcodes on vaccine packaging

The Tanzania Ministry of Health and Social Welfare is committed to enabling the tracking of vaccines movement from manufacturer to recipient through the use of reliable barcode technology, and in 2013 asked PATH, a global health organisation, to complete an implementation feasibility assessment.

Driving this initiative is today's reality where product lot and expiration information are captured manually on paper (copied from vaccine packaging); the constant monitoring of the cold-chain is a real challenge; refrigerators are often stored in cramped conditions with different types of vaccines stacked on top of each other; and there are challenging logistics issues which limit the tracking of vaccines especially in remote areas.

That is why a proof-of-concept project has been launched to address these challenges.

- Pfizer decided to include GS1 barcodes on their vaccines shipped to Tanzania as of February 2014
- Other manufacturers are also committed to deliver vaccines with barcodes following the recommendation
- Gavi is funding the development and testing of software prototypes and hardware profiles in Tanzania
- WHO Vaccine Presentation and Packaging Group has recommended the use of barcodes conforming to GS1 standards and specifications.

Overall positive feedback has been received with national, district, and regional immunisation officers seeing the additional value of implementing barcodes.

The next steps will be to incorporate the barcode functionality into national systems and perform an independent evaluation to measure impact.

**For more information, download the conference presentation.**

Join us in

# Mexico

## for the next Global GS1 Healthcare Conference

## 21 – 23 April 2015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