Automation and Traceability Pilot in Public Health System, Early Results, Regulation and Next Steps

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AGENDA

1. Before and After the Pilot
2. National Healthcare Products Catalog
3. Difficulties and main Issues for the project
4. Local Manufacturers and Distributors Working Team Priorities
5. Next Steps and Further developments
Why it’s important to begin now for the public health in Chile?
Some Current Numbers

- The Government Spending Budget and Pharmaceuticals was increased 100%, from 37M US$ to 74M US$. 25% of this expenses was recognized to not know were it finish.

- Common Inventory Visibility in Public Hospitals are around 70% or less (in front of 98% in retail), with annual budget near to 2M US$ in pharmaceuticals spending.

- Traceability it’s something that don’t exist, in a concrete and solid way.

- Estimates from Cenabast (Public Healthcare Distribution Center) talk about 400.000 US$ lost annually due product expiration and weak control of it. Public Hospitals also reports big numbers associated with this subject.
Auge Plan

• The system will guarantee some aspects:
  • Average Price for Intervention Predefined
  • Opportunity, maximum time frame to be treated
  • Access, to all the population segments
  • Quality, Type of products, and Controls
  • 25 Diseases Initially and 52 Diseases on 2007
  • Account Transparency for the Patient

• What means this new Plan:
  • Very good process efficiency
  • Strong Cost Control and Tracking is the Key to be Profitable
  • Automation and technology where it’s needed
  • Capacity to make comparisons between different Hospitals
  • Increase of 50% in Pharmaceuticals and Devices Budget
Two Working Teams

**Standard Classifying Team**
- To Define and Implement a Unique Standard Classification Scheme for the Health Public Sector in Chile
- 10 p

**Bar Codes Team**
- To Implement the Standard EAN.UCC System in the Health Sector, inside the Companies working in the Piloto Effort.
- To standarize the Product Code scheme along the Supply Chain
- 30 p
Companies Involved

Public Health System
- Hospital San Borja Arriarán (600 beds)
- Instituto del Cancer (350 beds)
- Hospital San Juan de Dios (650 beds)
- Hospital Roberto del Río (540 beds)
- Hospital Las Higueras, Talcahuano (410 beds)

Industry Support
Novofarma Dist Center (21% Market Share)
GRÜNENTHAL., BOEHRINGER INGELHEIM, BAGO S.A. (Argentino), PFIZER, ANDROMACO, ASTRAZENECA, LUMDBEK, NOVONODISK, J&J (Consumables Line)

BayService Dist Center
Alcon, Bristol-Myers Squibb, Pentafarma (Fresenius, Alemania), Organon, Schering Plough, Wyeth, Bayer
Before and After the Pilot
Pilot Status, 12 Months Before

- **Cenabast (2)**
  - Not Standard code
  - Not use of Bar Codes

- **Laboratories (20)**
  - Not Standard code
  - Not use of Bar Codes

- **Hospital (3)**
  - EAN Standard Code
  - No use of EAN inside Hospitals
  - Generic Product Registry
  - No Control of Expiry Date and Lote Number
  - Weak Cost Control

- **Patient (4)**
  - Traceability don’t exist

(1) (2) (3) (4)
Unit Dose
Internal Process
Pilot work today
3 Hospitals and Cenabast

Cenabast (2)
Laboratories (1)
Main Storage
Pharmacy
Clinic Service
Patient (4)

EDI Dispatch advice
• EAN.UCC Codes
• EAN-128 on Boxes

EDIS Dispatch advice
• EAN Standard Code
• EAN-128 on Boxes
• RSS/CS ó Datamatrix in Unit Dose

Traceability Chain Integrated (Track and Trace) (Multi-Hospital Model)

Pediatric UCI

• Exact Product Registry
• Lote and Expiry Date Control along logistic chain
• Cost Control by unit, not generic

Manual Unit Dosis
Datamatrix Use

Backward
Forward

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EAN-128 Coded Boxes from Cenabast
Complete Traceability to the bed !!
Centralized Catalog of Health Products
National Unique Catalog for Health Products

- **EAN.UCC Containers Codes - Boxes and Pallets**
- **EAN.UCC Codes - Base Unit**

<table>
<thead>
<tr>
<th>MANY PACKING correspond to one BASEUNIT</th>
<th>ONE ISP REGISTRY it’s composed of many Active Ingredients</th>
</tr>
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<tbody>
<tr>
<td>18,500 Packing Units Catalogued</td>
<td>13,000 ISP Registries</td>
</tr>
<tr>
<td>13,000 Base Units Catalogued</td>
<td>13,000 ISP Registries</td>
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<tr>
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<td>22,000 Active Ingredients</td>
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</tbody>
</table>

**1 a 1**

- **ISP Registry Code**
- **UNSPCS Classif Chilecompra**
- **ATC Classif Active Ingredients**

**GS1**

One Base Unit Correspond to One ISP Registry

**ISP**
7800004251247 = Code Find in the Catalog

<table>
<thead>
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<th>Clinic Table (ISP Responsibility)</th>
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<tr>
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</table>
GS1 Chile
Support Operation
PHASE 1

Quality Assurance

GTINs Synchronization

GTIN Assigned

New GTIN Requirements

GTIN Review

Manufacturers

GS1 Chile Catalog

Hospitals

CENABAST

Errors Correction

Products Transportation

Dispatch Advice
DESADV /EDI

Products Transportation

Dispatch Advice
DESADV /EDI
New Product Introduction Process

1. GTIN Assignment
2. Description (Photo, Measures, ...)
3. ISP Number
4. Quality Description Assurance Process

Health Catalog

GS1 Chile

ISP Regulatory Body

Supplier

- ISP Number
- GTIN
- ATC Classification
- UN Classification

1. ISP Number Assignment
2. Clinical Trials
3. Documentation

Hospitals

Chilecompra

Others

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Status Summary of the Project
Some KPIs ….

INVESTMENT TO DATE

- US$ 450.000.-, for all the participants

CENABAST DIST CENTER

- Truck waiting and unload time from 4 hours to 1 hour
- People involved in reception from 4 persons to 1 person
- Lote and Expiry Date Coded and Automatic Capture
- Change of Stocks Management Policie to FEFO, guaranteed

CANCER INSTITUTE HOSPITAL

- Saving of 30% in working time for Storage and Pharmacy personnel
- Faster Truck unload time
- Detection of Early Product Expiration
- Guaranteed FEFO policy in Patient Prescription (on the Bed Side)

And we are getting more ….
Summary and Conclusions

**PHASE 1:**
- Code of Boxes and Units Base
- Code of Number of Lot and Date of Expiration in the packing
- Use of EAN-128, DUN-14, EAN-13 + 2D
- Electronic Message of Dispath/Reception Advice

NOVEMBER 2005

**PHASE 2  (According Industry Working Group)**
- Code of Unidosis or dose of administration to the patient
- Use of RSS+ Composite

DECEMBER 2007, IT’S A MUST

*For Health Authorities, Unit Dose solution it’s an Industry Solution, not a Hospital Process….*
Status at the beginning

- Bad data quality and alignment in laboratories master files
- Not use of expiry date and lote coded, specially from Local Manufacturers.
- Not use in the public health logistic channel of codes coming from manufacturers, and re-labeling of products
- Traceability line broken, in terms of lote and expiry date pass along the distribution channel.
- No logistic EDI electronic messages in use
- Manual registry and process of products in public health distribution center and hospitals
- Different product identification and classification in each public hospital
- Generic Product Cost Control associated with Patient Bill and Registry Controls
After Ten Months of Team Working
Starting Pilot Phase

• Data Quality assurance process with 80 Laboratories master files
• Implementation manual sponsored by Public Health Minister recommending EAN-128/RSS on all cases and unit-dosis
• ReLabeling it’s out !, all product identification must come directly from manufacturers using GS1 standards
• Use of EAN-128 and RSS/CS to pass Lote and Expire Date across the logistic channel
• Use of EDI Dispatch Advice to automate receptions and information flow
• Barcode Technology Implementation in Three Hospitals and Central Distribution Center, to automate the product information capture and registry.
• Unique Catalog and Classification for the Country sponsored by local regulatory authorities
• Unique Product Cost Control associated with Patient Bill and Registry Controls using EAN codes.
Local Manufacturers Working Group (LHUG ?)
Participants

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<tr>
<th>#</th>
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<td>1</td>
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Agreements and Next Steps

- PHASE-1 Implementation push
  - Identify GAPs in the Logistic for each player
  - Formalize Agreement with all the Players
  - Add the Private Hospitals Sector to the Initiative

- Evaluate Feasibility to Unit Dose
  - International Industry Directions (HUG, FDA, etc)
  - Government Policies and Regulation Needed to support it
  - Economic Model to explain Hospitals and User about Benefits and Cost (Business Case), and also authorities to bring rationale to discussion

- Educate the Industry about standards and international agreements about it

- To form a Working Steering Committee, to align relevant players
Balance Analysis Between Unit Dose Cost and Health System Savings...

We need to find it ….. !!! (quickly !)

San Borja Hospital analysis shows US$160,000.- annual savings doing the unit dose project internally
Difficulties and New Initiatives
It’s not enough to have unit dose . . .

1. Track Devices Use
2. Track Professional Time
3. Support Traceability
4. Products Cost Assignment
New Initiatives

- HAND HELD, Generic Application to Control the process around the Patient Bed, with generic interfaces to hospital systems
  - Based con CASE MIX Methodology (Medical)
  - International Disease and Risk Classification
  - GS1 Identification Standards

- Health Consumibles and Devices Products
  - ISP - GS1 working group to add this area to the national catalog

- World Bank Fund oriented to Medium and Small Hospital
  - e.Procurement Platform
  - Logistic Automation and Traceability
  - Unit Dosis Pilot Facility
• In the beginning, no one knows about GS1 Standards. Specially Hospitals and Health Personnel
• Hospitals are not so aware for their own process and cost
• The support in the implementation phases to hospitals need to be closely
• We found many problems in the Master Files of Laboratories, when customers started to use it directly.
• It’s a good idea to start Visiting Manufacturers Facilities to Assess the Real Challenge for them, to PHASE 1 and PHASE 2, from the beginning
• *If you don’t have an Industry over 90% ready on GS1 standards and a Centralized Catalog Ready, forget about and initiative like this.*
What we need from the HUG Participants !!!
HUG Support

1. Help to Solve PHASE 1 Challenges
   1. Printing Solutions in Production Line
   2. Solutions Suppliers Tested by HUG Participants

2. Directions to Unit Dose
   1. A Clear Path to the Future about Datamatrix use and EPC/RFID tags timing
   2. Find the new equilibrium model

3. Chilean Subsidiaries Support and Direction
   1. Communicate HUG activities and Direction to your Distribution Channels
   2. Push them to support local initiatives aligned with global product strategies
THANK YOU
FOR YOU ATTENTION !!