Data as the base for the supply chain

Building the foundation

Lagos, Nigeria
18 September 2019
Speakers

• **Alan Bornbusch**, Division Chief Commodity Security and Logistics Division, USAID

• **Stew Stremel**, Enterprise Architect, RHSC

• **Ugbede Abu**, Supply Chain Advisor, USAID Malawi

• **Tania Snioch**, Director, Healthcare, GS1 Global Office

Alan Bornbusch

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You Can’t Manage What You Can’t See

Alan Bornbusch
GS1 Conference, Lagos, Nigeria
18 September 2019
Long History of Supply Chain Visibility

Forecasting

Procurement & Orders

Shipments

Consumption & Stock

RH Interchange

CARhs group

PPMR

Coordinated Supply Planning group
Many connect to many.
Many connect to many. Many connect through one.
GFPVAN & Countries

Manufacturers and Suppliers
Shippers
Ports and Customs
Central Medical Store
Regional Warehouse
Health Facility / Hospital Clinic
Beneficiary
The GFPVAN Today

**Better** = technology = E2open

**Aggregate** = data standards = GS1 alignment
• 1,561 orders and 1,578 shipments, for 7 products and 98 countries

**Share** = policy = 1 Terms of Use for all users

**Align** = people = 1 central governance structure
• 2 countries (Malawi, Nigeria), 2 global procurers (USAID, UNFPA), 4 manufacturers (implants, orals)
GFPVAN and GS1
Malawi

- Primary Value Drivers
  - Use of order/shipment tracking from manufacturer to arrival in Malawi to plan storage and distribution in advance.
    - GFPVAN alerted the MOH of a shipment delay, and they were able to redistribute stock between facilities in Malawi and avoid stock-outs.
  - Observe supply availability and use in quantifications
    - GFPVAN flagged over-forecasting for implants and the data was used to properly adjust the quantification forecast.
  - Request rescheduling of shipment delivery
    - Malawi users can use data in the GFPVAN to look at shipment scenarios and create tickets that directly alert procurers to the need for expedited, delayed or canceled shipments.
Nigeria

• Primary Value Drivers
  • Direct visibility into donor orders/shipments (no phone calls/emails required!)
    • Nigeria users have reported how order/shipments data in the GFPVAN allows them to quickly develop reports without having to call or email others for missing data
  • More informed conversations with partners in-country regarding needs (can reference PO#’s)
    • During coordination meetings, participants are now able to reference exact purchase order numbers to more effectively hone decision-making.
Stewart Stremel

Enterprise Architect

Stewart’s background is in Anthropology and Archeology with a Master’s in Systems Theory and Leadership. His interests are in understanding how technology and culture interact and how to create the conditions that allow organizations to bring about positive change. He has the good fortune to have been a software developer, white-hat hacker, infrastructure architect and a enterprise architect and has more than 20 years of experience specializing in designing, analyzing, scaling and supporting enterprise-wide Solutions. This rich and varied background lends perspective to his work for both the technical components and there impacts on people.

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Enabling system change and transformation by removing barriers in product master data

The Global FP VAN and Data Standards

Stew Stremel
GS1 Conference, Lagos, Nigeria
x September 2019
GFPVAN - Common Catalog Challenges

1) Problem Statement:
Inability to integrate between multiple application/systems that have different product coding methods

2) Problem Statement:
High degree of error and effort to maintain product definitions that are aligned between multiple systems (often maintained by different organizations)
GFPVAN Product Harmonization

Manufacturers

Procurers

Countries

SMOs

Data Management

GFPVAN App.

Transactions:
- Orders / Shipments
- Inventory / Supply Plans

GFPVAN

Log
Enrich
Approve
Publish
**GFPVAN Architecture**

- Manufacturers prepare their master data for their products.
- These are either being “published” manually to countries via the registration process or via GDSN.

1. Manufacturers prepare their master data for their products.
2. GDSN data from the manufacturer is now available on the GDSN network.
3. Countries select which organization(s) will manage the PCMT instance.
4. Countries subscribe to GDSN data and it is automatically imported into the system.
5. For Non-GDSN products an initial import for existing systems is done.
6. Alternatively - Data definitions could be imported from Global Sources.
7. After this countries can make a decision on where they would like to control the data entry of future new records.

- GDSN entries (GTINs) can be mapped to existing product identifiers as needed.
- Multiple GTINs can be mapped to a single country product/trade-item identifiers.
- Enrichment of attributes can now be assigned for country specific data such as:
  - Regulatory code
  - System codes
  - Insurance prices
  - Etc...
- As data is published it is available for exports and/or API integrations.
- The API is well positioned to work with an OpenHIE implementation and support a country’s interoperability layer.
- Existing systems do not need to be redesigned to take advantage of the product master.
- They have the ability query using any identifier being used in-country (such as OpenLMIS code or DHIS2 identifier).
- Barcode scans or legacy ID codes of an existing product can gather the necessary attributes that facilitate integrations.

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**Interoperability layer**

- OpenLMIS
- DHIS2
- ERP
- Barcode Scan
The “Why” vs. the “How”
Country Product Catalogs - Preparing a platform for use

1) Problem Statement:
Inability to integrate between multiple application/systems that have different product coding methods

2) Problem Statement:
High degree of error and effort to maintain product definitions that are aligned between multiple systems (often maintained by different organizations)

3) Problem Statement:
Inability to scan GS1 barcodes on commodity package labels, to improve efficiency, data quality and to facilitate track and trace
PCMT - building a platform for success
For More Information

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RHSC Global FP VAN website: https://www.rhsupplies.org/gfpvan
Ugbede Abu is the Supply Chain Advisor for USAID Malawi Health office. He is a pharmacist and public health professional with over 20 years of specialized experience in health and pharmaceutical systems strengthening in international settings. Mr. Abu provides strategic, technical leadership and programmatic guidance to public health programs in Malawi, working to ensure an uninterrupted supply of lifesaving medicines and health products among target population.

Mr. Abu previously worked for USAID Nigeria as Pharmaceutical Commodities Logistics Manager and technical lead for its PEPFAR supply chain program, one of U.S. Government’s major supply chain portfolio for HIV/AIDS prevention and treatment worldwide. His expertise includes supply chain management, leadership and strategic planning, program design, implementation, monitoring and evaluation, quality improvement and risk management.

Mr. Abu holds a Master of Public Health from University of Limpopo, Medunsa Campus, South Africa and a Bachelor of Pharmacy degree from Ahmadu Bello University, Zaria, Nigeria.

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Data as the base for the supply chain
Malawi National Product Catalogue Initiative

2nd African GS1 Healthcare Conference
Lagos, Nigeria

Ugbede Abu
USAID Malawi
September 18, 2019
Agenda

1. Background- Malawi
2. Pharmaceutical Supply System
3. As is-Product data flow
4. Problem statements
5. To-Be Product data flow
6. National Product Catalogue
7. Conclusion
Malawi: Background

- Population approx. 17,563,749 million\(^1\)
- About 85% of population is rural
- Heavy disease burden (HIV, TB and Malaria)
- HIV prevalence among adults (15-49 years) 9.2% as at 2018\(^2\)
- GDP per capita (2018): $389 (Zambia $1539; Nigeria $2028 and South Africa $6339)\(^3\)
- Free healthcare services at public health facilities
- Vertical health supply chains and data systems

\(^1\) Malawi National Statistical Office  \(^2\) UNAIDS  \(^3\) World Bank
We need GS1 and NPC to effectively manage an integrated supply chain system.
• Physical commodity moves from one supply chain partner to another,
  o Whereas product data & information associated with this commodity does not
• Each SC partner maintains its own set of information affecting data consistency & quality,
  o Thereby limiting end-to-end data visibility, traceability & the ability to plan effectively
Country Product Catalogs – Preparing a platform for use

1) Problem Statement:
• Inability to scan GS1 barcodes on commodity package labels, to improve efficiency, data quality and to facilitate track and trace

2) Problem Statement:
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To-Be Product Data Flow

In-Country Flows

Product Creation
1. Register Product & Capture Details
2. Publish Product Details automatically

Data Governance
1. Updates/Changes automatically sent
2. Changes reviewed and approved or rejected or adjusted

Maintaining Single Version of Truth
1. Changes propagated to all supply chain levels and systems

Manufacturers

Product Information (provided manually)

GDSN

PMPB
Access DB

CMST

OpenLMI

DP & SDP

Health Facilities & Hospitals

Private Sector Various Systems

Community Health Workers

Patients

National Product Catalog

Product Information published as pdfs, brochures etc. in the absence of access to systems

Arrow Legend

Automated
Manual
Future

Future
Conclusion

• Supply chain systems are complex but manageable
• Leverage data and National Product Catalogue to improve supply chain performance
• Stakeholders must align their data improvement plans to achieve common strategic goals
• We need strong partnerships to adopt and implement potential game changers: National Product Catalogue, Global VAN and GS1 standards
Thank You
Tania Snioch

Director Healthcare

Responsible for overall GS1 Healthcare operations, special projects and GS1 Member Organisation (MO) support.

Have assisted the Australian Healthcare industry to implement GS1 standards through a range of state, territory and federal initiatives.

Have an Honors degree in Biomedical Science from Monash University in Melbourne.

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Australia’s journey to accurate and consistent master data in healthcare

Tania Snioch, Director Healthcare, GS1 Global Office
A large country – approximately 4.0 hour flight from north to south, 4.5 hours from east to west

A population of approx. 25.26 million

Most of the population around the coastline, with many small (very remote) towns and semi-nomadic populations

Major cities with manufacturing, importing, supply and distribution are in the south east
Both our political and healthcare systems can be complex

- We are a federation of 6 states and 2 territories, with 1 federal government
- We have private and public health services – approx. 70% is publicly funded; approx. 30% privately funded
- Public healthcare delivery is a mix between the 8 State & Territory Governments (Health Departments) and Federal Department
- According to the federal Department of Health\(^1\), our health system challenges include:
  - an ageing population and increasing demand on health services
  - increasing rates of chronic disease
  - costs of medical research and innovations
  - making the best use of emerging health technologies
  - making better use of health data

How and why did we start our master data journey...

- In December 2004, Deloitte delivered to the governments the *Recommendations for National IM&ICT Enablers in the Health Sector Supply Chain* report.
- This report stated: “Full implementation of the NPC will save the public healthcare sector at least $AUD200 million per annum by ensuring accurate, valid and up-to-date product data, and improved communications and supply chain operations”\(^1\)

- In 2005 the The National E-Health Transition Authority (NEHTA), a company established by the Australian, State and Territory governments, was formed.

- A work plan was agreed...

\(^1\) Presentation by Mark Brommeyer, Manager Supply Chain, NEHTA, October 2012
What was NEHTA’s role?

- NEHTA was tasked to 'develop the standards and provide and manage the development of infrastructure, software and systems required to support connectivity and interoperability of electronic health information systems across Australia' and it has achieved that.

- This includes development and implementation of the key building blocks for a national eHealth system including standards and specifications; identity management; security and authentication; disease and medicines terminology; secure messaging; clinical safety assessment; conformance and compliance management; and procurement and supply chain solutions.

Supply chain reform was needed because...

1. Lack of standardised product identification
2. Lack of standardised location identification
3. Multiple product data catalogues being maintained per hospital, per hospital network and per state

Poor supply chain costs the health system money:
• Wrong product ordered/delivered
• Wrong quantity/poor forecasting and inventory management

Automating processes enables supplier and buyer organisations to:
• Reduce redundant purchasing tasks
• Improve inefficient work practices
• Achieve greater accuracy in procurement and tendering

Source: Presentation by Mark Brommeyer, Manager Supply Chain, NEHTA, October 2012
The National Product Catalogue

• The National Product Catalogue (NPC) is a way for suppliers to provide standardised and accurate product and price data electronically to the Australian health departments and private hospital providers.

• The NPC provides suppliers with a single mechanism to communicate structured catalogue data to many health customers – and the health customers a single way to access this data from multiple suppliers.

• The NPC enables synchronisation of product and pricing data for accuracy in electronic procurement.

Source: Presentation by Mark Brommeyer, Manager Supply Chain, NEHTA, October 2012
Key Data on The National Product Catalogue

A Trade Item

- Identifiers
- Descriptions
- Packaging
- Dimensions
- Dangerous Goods
- Classification
- Dates & Ordering
- Healthcare Attributes
- Pricing & Tax

Source: GS1 Australia
Progress over time... GTIN records
October 2012 – August 2019

Source: GS1 Australia
Progress over time... Suppliers of data
October 2012 – August 2019

Source: GS1 Australia
Quality data is key

16 August 2019

Suppliers improve health service data

HPV acknowledges the efforts of top performing suppliers who have been working hard to deliver high quality data in the National Product Catalogue (NPC), a key source of product information for Victorian health services and the new Common Catalogue.

Some recommendations from my experience

• Communicate WHY a national product catalogue is important for your organisation— not just for supply chain but to enable patient safety
• Align with globally harmonised standards and the global trend towards these
• Ask for what is needed, not ‘what would be nice to have’
• Don’t work in isolation – partnership and collaboration will lead to better outcomes
• Be clear about expectations from the start and keep these consistent
• Educate, communicate and celebrate success
• Work with those organisations who are having challenges – there is always a solution
• Cater for small and large organisations – both suppliers (providing data) and hospitals (receiving data)
Safer, more efficient care starts with a simple scan...

But when you scan a barcode, you need to be sure this accesses a database that contains accurate, complete and timely information.

And THAT is what a National Product Catalogue can help facilitate!
Mr. Van den Wouwer has a Master in Bio Engineering and Master in Industrial Management Sciences. He worked for 15 years at Mars Inc. In various Supply Chain Management functions. In 2007 he joined Johnson & Johnson in the planning department, leading the chemical platform planning department. Since 5 years he is responsible for Serialization and Traceability deployment in EMEA region where he has successfully implemented the European regulation for Medicines Verification. Since 6 months he is also in charge of Unique Device Identification and Global Data Synchronization across EMEA.

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Global Standards and Data Quality

Basis for a secure supply chain

Dirk Van den Wouwer
EMEA Deployment, Digital Identification &Traceability
GS1 Healthcare Conference, Lagos, Nigeria
September 2019
Johnson & Johnson

World’s largest and most broadly based healthcare company

- Over 130 years of caring
- Approximately 130,000 employees worldwide
- Every day, more than a billion people around the world enjoy the benefits of Johnson & Johnson’s products and services
Johnson & Johnson Portfolio

Consumer
Self Care • Skin Care • Essentials

Medical Devices
Wound Closure & Surgical Devices • Minimally Invasive Surgery • Joint Replacement Sterilization • Eye Health • CSS

Pharmaceuticals
Oncology • Infectious Diseases & Vaccines • Immunology • Cardiovascular & Metabolism • Neuroscience & Pain • Pulmonary Hypertension • PAH
Our Credo

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs, everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers’ orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive working environment where each person must be considered as an individual. We must respect their diversity and dignity, and recognise their merit. They must have a sense of security, fulfilment and purpose in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must support the health and well-being of our employees, and help them fulfill both their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders, and their actions must be just and ethical.

We are responsible to the communities in which we live and work, and to the world community as well. We must help people to be healthier by supporting better access and care in more places around the world. We must be good citizens – by supporting good works and charities, improving health and education, and bearing our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programmes developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realise a fair return.
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<th>Importance of using standardized data</th>
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<td>European Union Falsified Medicines Directive (FMD) data requirements &amp; harmonization efforts</td>
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<tr>
<td>Product data for medical devices: Unique Device Identification (UDI), Food and Drug Administration (FDA) regulation, Medical Device Reporting (MDR) regulation</td>
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<tr>
<td>Global Data Synchronization Network (GDSN) as a standard for sharing data</td>
</tr>
<tr>
<td>Importance of data quality</td>
</tr>
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</table>
Importance of Using Standardized Data
Implementing traceability
Traceability Entails Integrated Systems & Processes Approach

Enabled by GS1 Global Standards (GTIN, GLN, SSCC, EPCIS)

Enterprise Serialization & Traceability System (EPCIS based)

- Regulatory Reporting
- ERP/WM
- Pack Line / Device
- 3PLs, CMOs, Wholesalers, ...
- Harvesting GTINs
- Validating GTINs
- Enumerating
- Populating GTINs
- Enterprise Data Management
- Artwork – Labelling & Enterprise Standard
Harmonization through End-to-End Network
Complex network involving numerous nodes and connections

Example Europe
• >2300 MAH / 1600 companies
• 7285 distributors / wholesalers
• 135,000 pharmacist

One common language!
Different Patterns in Regulations Create a Patchwork

Result - extra complexity, development costs, implementation time and risk
Importance of Standards

The world is a global village, let’s speak the same language

Internal Communication

- Multiple sectors
- Multiple regions
- Different ERP systems

External Communication

- Regulatory instances
- External manufacturers, distributors, 3 PLS
- Trade organisations, wholesalers, pharmacies

Avoiding Operational Complexity

- Manufacturing & distribution for different regulations
- External manufacturers producing for different Marketing Authorisation Holders

Mergers, Acquisitions & Divestitures

- Decrease transition complexity when adhering to standards

Interoperability

- One networked company IT system environment
- One IT development for each deviation
- Linking product codes reduces complexity
EU FMD Data

Requirements and harmonization efforts
Turning EC FMD Regulation into European Industry Standard
EFPIA recommendation for coding of pharmaceutical products in Europe

DataMatrix – Coding proposal derived from GS1 standards

Manufacturer Product Code (GTIN or NTIN): 14 digits
Unique Serial Number (randomized): up to 20 alpha-numeric characters
Expiry Date: 6 digits (YYMMDD)
Batch Number: up to 20 alpha-numeric characters

+ Minimum requirements on quality of randomisation

EEA License Plate Example:

GTIN: 012345667891283
SN: 123456789012
EXP: 12-2018
LOT: 123456

(01) 012345667891283
(21) 123456789012
(17) 122018
(10) 123456
Harmonizing Unique Identifier in European Economic Area
Trending to GS1/EFPIA recommendation

GS1 GTIN – EFPIA recommended
(UK, Ireland, Czech Republic, Slovakia, Latvia, Lithuania, Estonia, Malta, Belgium, Netherlands, Romania, Bulgaria, Croatia, Hungary)

NTIN AND GTIN allowed or will evolve to GTIN
(Scandinavia, Iceland, France, Poland, Switzerland, Slovenia)

Include National Reimbursement Number in 2D Data Matrix
(Spain, Portugal)

NTIN for Country Packs
(Austria, Germany)

Countries implementing at later date – coding discussions ongoing
(Greece, Italy)

GTIN (01) + Product / Market specific Data

NTIN

GTIN database

Product Code = National Number

GTIN (01) 09504000059118
EXP 20 Nov 2014
Lot (10) 7654321D
SN (21) 10987654321

+ Product / Market specific Data

#JJSCDigital
Harmonizing Unique Identifier in European Economic Area
Trending to GS1/EFPIA recommendation

![Diagram of GTIN database with product code and market data]

- **Product Master Data**
  - Product code
  - Coding scheme
  - Name
  - Common name
  - Pharmaceutical form
  - Strength
  - Pack type
  - Pack size (Dose Count)
  - Product Code Status
  - Product Code Version

- **Product per Market Data**
  - Member state ISO ID
  - National code
  - Article 57 code/PCID (TBC)
  - MAH ID
  - MAH Name
  - MAH Address
  - Serialisation Flag
  - List of Wholesalers with ID, name and address who have a written contract with the MAH above

- **Batch Data**
  - Batch number
  - Expiry date
  - Manufacturer ID
  - Manufacturer Name
  - Manufacturer Address
  - Batch Number Status

- **Pack Data**
  - Serial Number
  - Serial Number Status

**Additional Data**
- GTIN Database
- Product Code: 09504000059118
- National Number: 1312345678913
- + Product / Market specific Data
Product Data for Medical Devices

UDI, FDA regulation, MDR regulation
US FDA & EU MDR Regulating Medical Devices
Identification & Data Sharing
Ensuring trusted data and traceability throughout the supply chain

Data Repositories

Label Requirements

Direct Marking
UDI Benefits
Patient benefits before, during, and after their surgical procedure

**Pre Surgery**
- **Authentication** - Identify counterfeits and ensure only genuine products are used
- **Product Availability** - Improve supply chain efficiencies

**During Surgery**
- **Safety**
  Only appropriate devices are used for the procedure

**Post Surgery**
- **Knowledge**
  Accurate identification of devices for performance analysis
GDSN: A Standard for Sharing Data

USAID anti-HIV, Stop TB programs
GDSN
Improving OTC and supply chain efficiencies by sharing product content with our customers

- Established in consumer retail ~12 years
- Significant growth in medical devices last 5 years
- Initial pharmaceutical pilot 2018 – start using in production for USAID/IDA GDF (End 2019)
GDSN - A Strength in Global Content Strategy
Collaboration between J&J Supply Chain and customers critical for aligning & improving data

- Treat product data as a highly-valued digital asset as we treat our products
- Ensure conversion of physical data to electronic data
- Publish and maintain accurate product data for customers across the globe – via GDSN
- Grow best practices across regions and segments
- Leverage standardized language of GS1
- Enabler of end-to-end connected visibility
J&J Supply Chain Provides Trusted Data
Supporting global health programs

One World Sync

- PREZISTA® (darunavir) tablets
- ONCE-DAILY EDURANT® (rilpivirine) tablets
- INTELENCE® (etravirine) tablets
- Sirturo® bedaquiline (100mg tablets)
Importance of Quality of Data
Trusted Quality Data is Imperative
Aim for 100% accuracy & alignment

Enables secure / efficient supply end-to-end; facilitating traceability and digitization of supply chain

- Automatic identification & data capture & electronic data sharing
- Standardization of processes and operations facilitated by consistent pack labeling
- Harmonization of product masters across systems & across partners

Ensures transparency / end-to-end visibility

- Fight product diversion – right products – right place – right cost
- Optimize inventory and taxation
- What, how much, where

Trusted products with trusted data

- Electronic data Catalogue (instant update possible all through the life cycle!)
- Improve data visibility by identifying products in a standard way (1 GTIN for 1 product)
- Consistent data quality across functions

Verification – matching label & barcode with database information

- Enable identification of every product supplied up until the patient
What Companies Need to Do

Learnings and advice

Understand regulatory requirements, liaise with regulatory bodies, exchange & educate

Focus on products and flows (what, where, who)

Collaborate & align across multiple functions & stakeholders (talk)

Aim for 100 % accuracy, take ownership

GO step by step (piloting is a good practice)

It is not a one time event

- Requirements must be built into SOPs and become part of base business activities

- Processes must be fully integrated into launches, new product introductions, acquisitions and divestitures

Use standards
Questions

• Alan Bornbusch, USAID
• Stew Stremel, RHSC
• Ugbede Abu, USAID Malawi
• Tania Snioch, GS1 Global Office
• Dirk Van den Wouwer, Johnson & Johnson
Visit the Marketplace during lunch time

Meet the exhibitors in the Mezzanine level of Orchid Hall

Every day during breaks and lunch
Thank you