Serialization deployment, a cooperation between Stakeholders
Our Approach is an early collaboration

We welcome initiatives to secure drug supply and enhance patient safety. Because it is in the interest of our patients.

It is not only a technical project

Success through a collaborative approach

We see the Serialization & Traceability challenge as an opportunity
Work **Togeth**er with All Stakeholders to Co-develop the National Verification / Traceability / E-health Concept

What needs to be DEFINED
- Standard Data Carrier
- Standard Data Construct
- Access to Data
- Reporting needs
- National database
- Implementation Timelines

The challenges are important

Success through a **collaborative approach**
*Manufacturers, Health Authorities, Associations, Peers, Trading Partners, Solution*
What is Required from MoH when Issuing a Traceability Regulation

Be clear about the requirement to be fulfilled. Articulate upfront!

Be mindful of implementation timelines: Realistically a 3-4 years horizon

Develop and implement an adaptable/ scalable technical solution based on international standards

What do you exactly want to achieve? How can we contribute?

Medicines verification e.g. Europe
Tracking & Tracing e.g. US, Turkey
Digitization of the drug supply chain
<table>
<thead>
<tr>
<th>Safety Feature &amp; level of application</th>
<th>Required by</th>
<th>Purpose (examples, non-exhaustive list)</th>
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</table>
| 2D-CODIFICATION                     | Hospitals, Regulators, Tenders | ✓ Reduce medication errors  
                                        ✓ Support e-supply-chain processes |
| Item SERIALIZATION                  | Sales pack  | Regulators                              | ✓ Verification at point of dispensing  
                                        ✓ Combat reimbursement fraud           |
| TAMPER Evidence                     | Sales pack  | Customers Regulators                     | ✓ Enhance pack integrity  
                                        ✓ Avoid re-use of packs               |
| AGGREGATION or Full Serialization   | Handling / Shipping units       | Regulators                              | ✓ Tracking & Tracing  
                                        ✓ E-pedigree  
                                        ✓ Logistics efficiency                |

A complementary set of Safety Features
Build a Solution Based on International GS1 Standards to Reduce Implementation Complexity, Duration and Costs

1. Leverage the significant investments Industry has already made in an effort to minimize impact on
   - Packaging networks
   - Distribution networks
   - IT Systems
   - Processes
   - People

Packaging lines to be upgraded
wholesalers, pharmacies, hospitals
New systems to manage data & events
From artworks to warehousing
Training effort is important

Product #: 09876543210982
Batch: A1C2E3G4I5
Expiry: 140531
S/N: 12345AZRQF1234567890

... to
   - Continue to supply high quality products to patients
   - Maintain a level of complexity which is still manageable
Implementation Workload can be More or Less High, Requiring Sufficient Time

2D Coding
- Standard Data (GTIN, exp. Date, lot/batch number)
- Online printing

Item serialization
- Serial # creation by Roche
- Data carrier: standard 2D, online printing
- Data construct: GS1 standard
- Without reporting to MoH

Example of deviation to standards
- Serial # management by 3rd-party
- Data carrier: linear, labeling
- Data construct: non-GS1 standard
- With reporting to MoH

Traceability
- MoH Reporting: special requirements
- Trading partners reporting: special requirements

Coding with specific data
- Labeling required

Standards
- 6 to 12 months
- 1 to 2 years
- 3 to 4 years

Implementation timelines
an extension in case of deviation to defined standards
Linking products with Data is a long journey

It requires a phased approach due to the complex interactive environment.

- Codification
- Serialization
- Aggregation
- Master Data
- Patients
- Products
- Database
- Reports
- Alerts
- Supply Chain
- Health System
- Pharmacovigilance

PILLAR 1
Cultural transformation for health data use

PILLAR 2
Digitalization and scale-up of priority health information system

Health Information System Governance
We remember GS1’s words: “It’s a marathon, not a sprint!”
Doing now what patients need next