Background for and purpose of survey

Assessing the Programmatic Suitability of Vaccine Candidates for WHO Prequalification (rev. 2014), preferred characteristics:

• Bar codes are recommended on all packaging levels used by manufacturers, with the exception of primary packaging, and should conform to GS1 standards and associated specifications.

• Bar code data should include the Global Trade Item Number (GTIN), lot number, and expiry date.

Criteria to transition to ‘critical’ for acceptance of new vaccines for PQ with next revision (3 years)

Purpose of issuing the survey to vaccine manufacturers supplying to UNICEF:

• Assess readiness of vaccine manufacturers to comply with a requirement to implement bar codes at secondary level in line with the WHO guidelines

• Identify potential risks of implementation to Vaccine Security – the uninterrupted supply of affordable vaccines of assured quality

• Based on input, to develop an implementation plan with timelines and milestones

Recommendation for implementation of bar codes in tenders since 2015, but not applied for evaluation
Scope and response rates

- Survey issued to 25 manufacturers with LTAs in place with UNICEF - 20 responded to the survey

- Response rates reflecting equally the composition of supplier base, around 80% from both manufacturers producing in developing countries and in industrialised countries

FOCUS AREAS
A. Technical Feasibility
B. Financial Implications
C. Drivers of Implementation and Lead Times
Outcome: Technical feasibility

- 85% of respondents already using GS1 bar codes
- Almost equal distribution between suppliers from developing and industrialized countries
- 100% of bar code users apply bar codes at secondary levels
  - 2/3rds also at shipping unit/tertiary level
  - 1/3 at primary level

**How many suppliers use GS1 barcoding**

- No
  - 1 Industrialized C.
  - 2 Developing C.
- Yes
  - 9 Industrialized C.
  - 8 Developing C.

N=20
Outcome: Technical feasibility

- 15/17 suppliers using bar codes apply the GS1 Data Matrix
  - ...but limited to specific combinations of products/markets based on market requirements
- For 2/17 suppliers not using GS1 Data Matrix, suppliers consider that current systems are not flexible to switch, and new systems will be required

Note: N=17. Data Matrix and Linear refer to GS1 standards
Outcome: Financial Implications

13/20 respondents indicate that i) one time investments will be required; and ii) increase in recurrent costs

Note: N=20
Primary reason for implementation is legal requirements in markets

Outcome: Drivers for Implementation and Lead Times

- Due to expected downtime during installment of equipment, the implementation of bar codes need to be planned well in advance to avoid interruption in supply
- 16/20 respondents indicated that it would be feasible to have bar codes implemented by 2022

Note: N=19
Conclusions on bar code survey and next steps

• Technical feasibility:
  • 85% of respondents are already using GS1 bar codes; all at secondary level, and some at primary and tertiary
  • 88% of those using bar codes are using Data Matrix, with 12% indicating that current systems are not flexible to adjust to this format

• Financial implications:
  • 68% indicates that investments are required and running costs will increase

• Drivers for implementation and lead times:
  • 58% indicates that key driver for implementation is legal requirements in markets
  • 80% indicates that it is feasible to meet the requirements by 2022

Due to the need to update packaging facilities, downtime is anticipated - careful planning across the supplier base will be required to avoid interruptions to supply
Conclusions and next steps

- Continuing efforts to improve supply chain efficiencies, and recognizing the benefits of the use of harmonized global or international identification and serialization standards on vaccines to improve visibility and traceability, UNICEF will add **bar codes as a mandatory technical requirement on the secondary packaging:**
  - In all tenders to be issued after October 1st 2019
  - To be implemented latest by 31st December 2021

- Further deep-dives through manufacturer consultations required to better understand lead times for implementation across vaccines supplied to UNICEF; and potential financial implications – to better plan for implementation across suppliers and reduce risks to supply

- An implementation roadmap will be developed in consultation with partners in the coming months
THANK YOU!