

Gavi Announcement

Vaccine Manufacturer GS1 Compliance

Gavi, the Vaccine Alliance is supporting countries to improve vaccine visibility and traceability from manufacturer to beneficiary, contributing to our efforts to secure quality assured vaccines delivered to the right place, in the right quantities, at the right time to all children and adolescents.

UNICEF and the World Health Organization (WHO) have recognised the benefits of the use of harmonised global or international identification and serialisation standards on vaccines to improve visibility and traceability. Since 2015, UNICEF has recommended the use of GS1 standards on the secondary package of vaccines. Gavi, the Vaccine Alliance is planning to require GS1 data and barcode standards on the secondary package to improve product identification, labeling, and data exchange within the immunisation supply chain. Starting 1 October 2019, for vaccine tenders backed by Gavi financing issued by UNICEF, it will be a requirement to have GS1 barcoding on the secondary packaging by latest 31 December 2021. An implementation roadmap will be developed in consultation with partners in the coming months.

In order to better manage the transition to apply track and trace system technology on vaccines to a labelling requirement, the WHO has convened a drafting group of Member States to develop a policy brief on traceability of health products. UNICEF has conducted a preliminary survey to inform the discussions of the WHO Expert Committee. Currently, UNICEF in collaboration with GAVI and other partners is conducting a more in-depth review to determine supplier readiness to comply with the GS1 standard on secondary packaging of vaccines and related products to ensure continued access.

As we move towards manufacturer GS1 compliance, we ask all development partners to fully support national supply chain partners and country implementors to improve visibility and traceability of vaccines from manufacturer to beneficiary.

Track and trace and visibility of vaccines can contribute to client safety, supply chain efficiencies and will support the overall goal of increasing immunisation coverage to support and drive universal health coverage. We look forward to working with all partners in the vaccine supply chain to make track and trace a reality and realise our collective commitments to the SDGs.

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As of 2014, The World Health Organization (WHO)^[1] recommended bar codes on all vaccine packaging levels used by manufacturers, except for primary packaging [on the vial], and recommended conforming to existing internationally recognised standards to ensure system interoperability, such as [GS1 global](#)

^[1] [Assessing the programmatic suitability of vaccines candidates for WHO prequalification, Revision 2014.](#)

WHO/IVB/14.10 Accessed on 18 March

2019: https://www.who.int/immunization_standards/vaccine_quality/ps_pg/en/

[standards](#) and associated specifications, and reaffirmed bar coding with Gavi partners in 2015.^[2] The use of bar codes, and GS1 standards and specifications, has long been viewed as one of the best approaches to improving vaccine visibility and traceability.

UNICEF procures enough vaccines and devices to reach 45% of the world's children under the age of 5 on behalf of governments, including both Gavi and non-Gavi funded countries, and supports country-level immunisation programme implementation.^[3] UNICEF has included WHO's recommendation in all its vaccine tenders since 2015, to allow industry to prepare for this potential future requirement.

The Gavi Alliance will support and work with key stakeholders and partners to update technical guidelines detailing label standards, placement, and appropriate references to the GS1 general specification, along with a phased implementation plan which outlines actions for GS1 compliance. This information will be released before a GS1 requirement is mandatory and will be informed by an industry survey.

In parallel, WHO is developing a policy position to be made available by the end of 2019 to provide high level advice for the national regulatory authorities on the use of track and trace technologies and standards, including GS1, in the supply chain of healthcare products, on the governance of the IT systems supporting this implementation, and on data management."

^[2] [VPPAG generic preferred product profile and workplan](#), March 2015: Accessed on 18 March 2019
https://www.who.int/immunization_standards/vaccine_quality/ps_pg/en/

^[3] Internet page: https://www.unicef.org/supply/index_vaccines.html accessed on 26 April, 2019