

# MEETING THE BAHRAIN COMPLIANCE DEADLINE: A VISUAL GUIDE

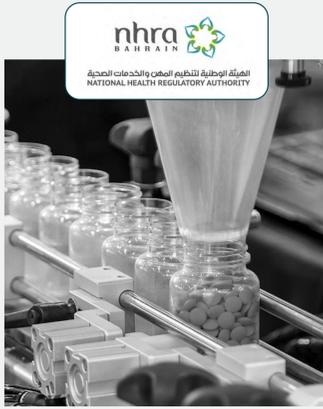


For companies that distribute medicines in Bahrain, the October 2021 deadline means that they must act quickly to ensure that they can continue to sell products in the Kingdom after October.

## WHAT IS THE SCOPE OF THE REGULATIONS?

### Which products are covered?

- Medicines registered with the Bahrain National Health Regulatory Authority (NHRA)
- Non-registered medicines with a temporary importation license
- Locally produced medicines
- Foreign-produced medicines imported as finished goods
- Imported medicines and medicines sub-packaged locally



### Which products are exempt?

- Free samples
- Registered Health Products with NHRA
- Approved alternative and complementary medicines
- Non-registered health products and alternative medicines

## WHO MUST REPORT?

The **INVOICING COMPANY** can be the manufacturer (MAH) or a separate company that handles distribution and invoicing.



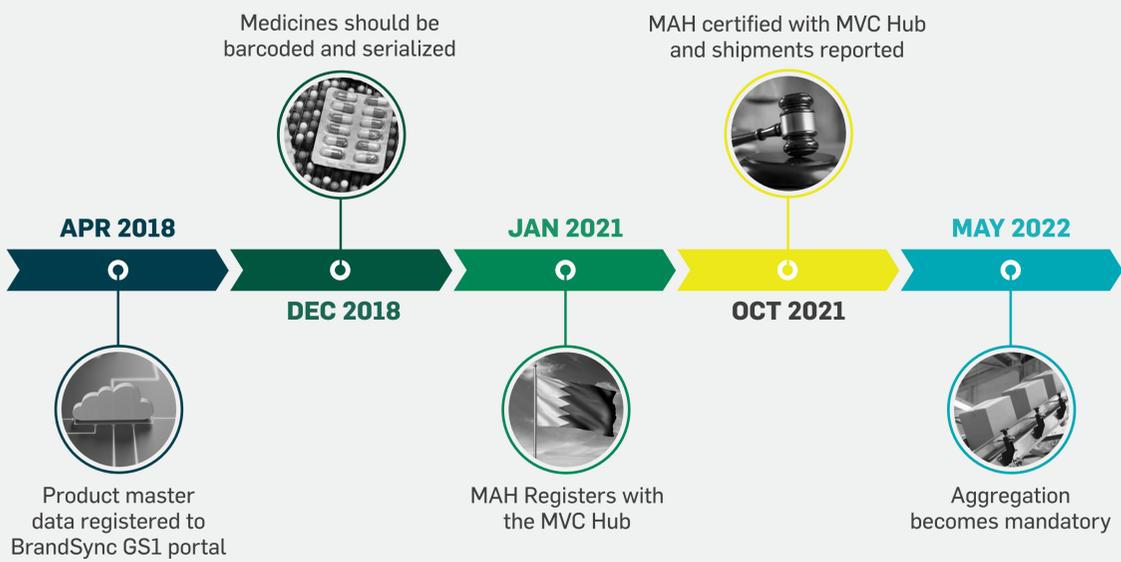
### The INVOICING COMPANY is responsible for:

- Submitting the required compliance reports to the NHRA-MVC Hub
- Sending the events captured on its behalf by a CMO, Repackager, or Third-Party Logistics provider
- Resolving discrepancies between the physical goods and what was reported to the NHRA-MVC Hub

### Reportable events include:

- Commission
- Packing
- Shipment
- Aggregation (2022)

## BAHRAIN COMPLIANCE TIMELINE



## BAHRAIN REQUIREMENTS AT A GLANCE



Barcoding



Serialization

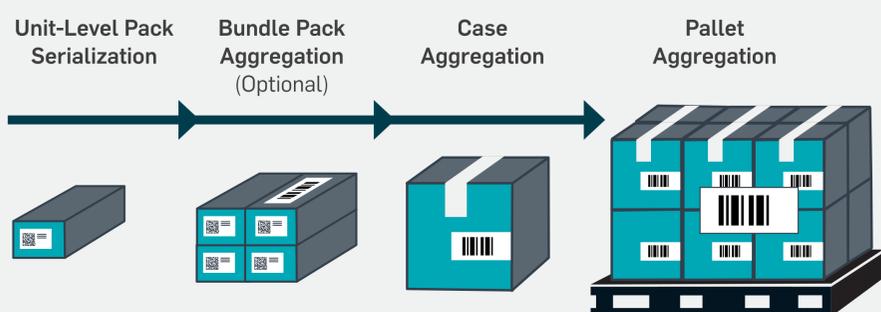


Traceability event capture



Reporting to NHRA

## CASE/PALLET AGGREGATION WILL BE REQUIRED MAY 1, 2022



End-state aggregation at time of shipment is expected. The maximum level of hierarchy accepted is 5 levels.

- Only packing events are reportable.
- Intermediate operational events in the warehouse are NOT reportable.
- Unpacking events are NOT reportable.

## COUNT ON TRACELINK FOR BAHRAIN COMPLIANCE

Every market mandate represents a new compliance challenge. As the world's leading provider of integrated track and trace solutions, only TraceLink offers the global regulatory expertise, proven product serialization solutions, and seamless partner onboarding and integration services you need for Bahrain compliance.



Contact TraceLink

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