

Questions	Responses
Will the BrandSync be connected to NHRA?	The NHRA-MVC Traceability Hub will have a connection to BrandSync to get Master Data for the Invoicing Company / MAHs
What are the EPCIS requirements for MAH? What EPCIS events will be required for a shipment to Bahrain?	The NHRA requires the Invoicing Company / MAHs to provide commission, aggregation and ship events.
BrandSync seems to be along the similar lines to the GS1 GDSN, which is also a data synchronization network for master data. Are they both similar? If we are GDSN compliant, do we still need to register with Brandsync?	BrandSync is not part of GDSN. Companies will need to register with BrandSync directly.
NHRA have mandated Aggregation from September 2021, how can compliance be achieved if Go-Live for NHRA-MVC Hub is October 2021?	The NHRA deadline to comply with the aggregation requirements September 01, 2021. The NHRA-MVC Hub must be receiving aggregation events no later than October 01, 2021.
Is the NHRA-MVC hub for Pharma products only or it will be implemented on health products and medical devices also?	The NHRA-MVC is for tracking Pharma products today.
If you aggregate locally, you will need to share other EPCIS events with the aggregation data.... We need to have a detailed document listing the EPCIS events to be shared based on business cases to allow us to prepare our systems and change our business processes	The NHRA requires the Invoicing Company / MAHs to provide commission, aggregation and ship events. If the aggregation is done locally, the aggregation event must be provided by the local entity. Yes, detailed information about the EPCIS events is available through the Technical Onboarding Guide.
NHRA MVC will be implemented for registered product with NHRA or products that are supplied on tender base	The NHRA requires barcoding and serialization for the following A. Products That Require Barcodes: <ul style="list-style-type: none"> • Registered medicines with NHRA. • Non-registered medicines, with valid temporary importation licenses from NHRA. B. Products That Do Not Require Barcodes: <ul style="list-style-type: none"> • Medicines free samples. • Registered Health Products with NHRA. • Approved Alternative & Complementary Medicines by NHRA. • Non-registered Health Products and Alternative & Complementary Medicines, with valid temporary importation licenses from NHRA. • Medicines cleared for secondary packing purposes (for local manufacturers ONLY)

<p>If we have multiple MAHs can we do only one registration?</p>	<p>Each Invoicing Company / MAHs or their regional office that has the contract to fulfil orders for Bahrain (or the legal entity that is responsible for supplying medicines to Bahrain) must sign-up with NHRA-MVC, sign a Participation Agreement with MVC, and pay the fees.</p>
<p>Will you provide details required for sign up so that the MAH's can gather this prior to completing sign up ?</p>	<p>We have provided the details regarding the sign-up process on the NHRA-MVC website https://www.nhra-mvc.bh on the Sign-Up Overview page.</p>
<p>The MAH could be the Global EU or US offices - any mandates from the NHRA-MVC team on this?</p>	<p>It is OK for the Global EU or US offices to be the Invoicing Company / MAH. The NHRA-MVC sign-up process is the same regardless of the office or location.</p>
<p>Is any customer/MAH with Tracelink connected already? Have you integrated with SAP ATTP L4 system?</p>	<p>NHRA-MVC has connected to all serialization partners, including SAP ATTP and Tracelink; but we have not started connecting L4 Systems for Bahrain yet.</p>
<p>Will the serial numbers in the 2D barcode be generated within the MAH or will MVC provide them to the MAH?</p>	<p>The NHRA-MVC does not provide any serial numbers or barcodes. The Manufacturing location is responsible for all serialization and labeling of the medicines being sold in Bahrain.</p>
<p>What will it happen for tender products, if it's not registered in Bahrain, how it will comply with GS1?</p>	<p>The NHRA requires barcoding and serialization for the following</p> <p>A. Products That Require Barcodes:</p> <ul style="list-style-type: none"> • Registered medicines with NHRA. • Non-registered medicines, with valid temporary importation licenses from NHRA. <p>B. Products That Do Not Require Barcodes:</p> <ul style="list-style-type: none"> • Medicines free samples. • Registered Health Products with NHRA. • Approved Alternative & Complementary Medicines by NHRA. • Non-registered Health Products and Alternative & Complementary Medicines, with valid temporary importation licenses from NHRA. • Medicines cleared for secondary packing purposes (for local manufacturers ONLY)
<p>When will you start master data migration from BrandSync? Is there a deadline?</p>	<p>The NHRA-MVC will begin connecting to GS1 BrandSync November 01, 2020 as Invoicing Company / MAHs begin their sign-up process. The integration between NHRA-MVC and BrandSync is a continuous connection to collect the Master Data. The deadline for NHRA-MVC Traceability Hub is January 1, 2021.</p>
<p>What will be the process to change in master data after an variation approval?</p>	<p>Please follow the BrandSync process. The NHRA-MVC will connect to BrandSync and continuously retrieve changes to Master Data.</p>
<p>We have a UK product that is registered with NHRA, we are not required to add serial numbers to each individual product for the UK market, are we able to just add one GTIN number to the packaging intended for the market in Bahrain rather than an individual number on each unit of product?</p>	<p>Please refer to the Bahrain Medicines Barcoding and Serialization Guideline. The expectation of the NHRA is that the first level of packaging (Primary Packaging) for the product is serialized either on the packaging or on a label affixed to the packaging.</p>

Should the registration be done by the MAH or the seller on BrandSync?	Each Invoicing Company / MAHs or their regional office that has the contract to fulfil orders for Bahrain (or the legal entity that is responsible for supplying medicines to Bahrain) must sign-up with NHRA-MVC, sign a Participation Agreement with MVC, and pay the registration and annual fees.
Once we register with NHRA-MVC Hub, and Master data has been migrated from Brandsync to NHRA-MVC, Can we discontinue using Brandsync?	Please refer to the Bahrain Medicines Barcoding and Serialization Guideline. The expectation of the NHRA is that all products are registered and maintained in GS1 BrandSync.
Could you please tell if products can have only 2D data matrix and no linear barcode from Jan 1, 2021, as some companies are requesting to remove linear barcodes on the packs in order to avoid supply issues	GS1 recommends 1 barcode on a pack, but it should be discussed with the NHRA before taking any action.
In regards to TraceLink, so all the reporting events will be through the compliance module of BAH?	Yes, Tracelink will send your EPCIS events to the NHRA-MVC Traceability Hub for Bahrain compliance.
With respect to the master data, if there are any divestment/acquisition will there be any specific guidelines to handle same?	Any changes to Master Data due to divestment/acquisition activity will be updated in BranSync. The NHRA-MVC will connect to BrandSync and continuously retrieve changes to Master Data.
We have a local distributor in Bahrain. So Responsibility to Register with NHRA-MVC is with Local distributor or MAH?	Each Invoicing Company / MAH or their regional office that has the contract to fulfil orders for Bahrain (or the legal entity that is responsible for supplying medicines to Bahrain) must sign-up with NHRA-MVC, sign a Participation Agreement with MVC, and pay the registration and annual fees.