FIMVO END USER AND ISV WORKSHOP

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AGENDA I

- EMVS System Overview
- What the Hub does (and how)
- Master Data
- Multi-Market Data
- Inter-Market Transactions

AGENDA II

- Connection Types
- Retrospective Uploading of Data
- Wholesalers and 3PL's
- Wrap-up Q&A

SESSION GUIDELINES

- Questions while I talk are great – helps with the flow
  - I might ask to delay a response if it's coming up in a later slide.
- Happy if you want to ask about things not directly covered – make use of having me here.
- Please remember that we are all learning.
  - There is a specification for EMVS (the infamous URS)
  - Reality says that a system of this size and scope is unlikely to be 100% described as we need in the URS – so we adapt when needed.
  - I'm here to learn as much as you are.

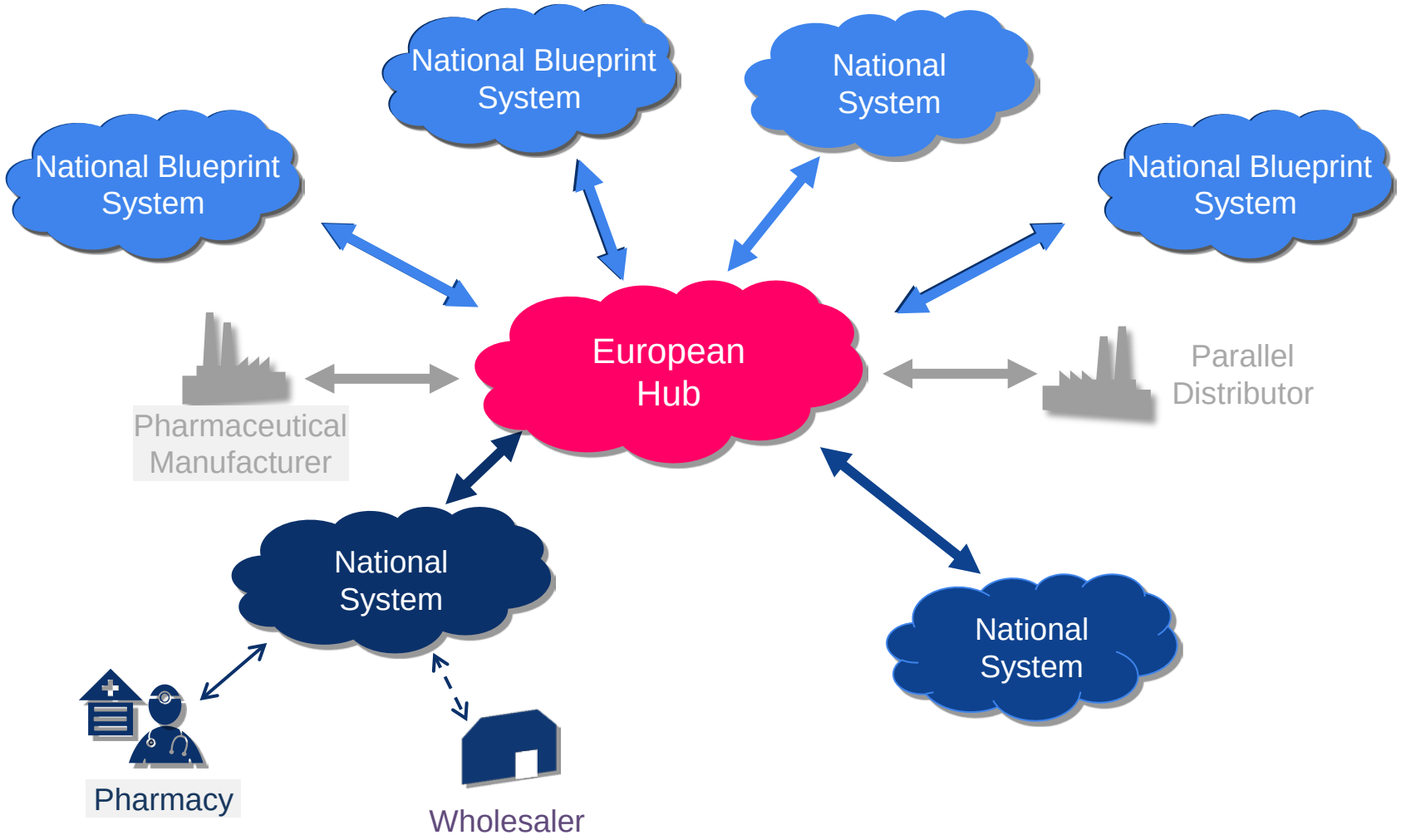
EMVS OVERVIEW

- EMVS is a DISTRIBUTED IT system.
- At its heart is the European Hub
  - All On-Boarding Partners (OBP's) (e.g. MAH's or MFR's) for original packs and Parallel Distribution connect to the Hub.
  - The Hub distributes data received from OBP's to the National Medicines Verification System's (NMVS).
  - The Hub manages 'Alerts' received from NMVS's and sends them to the relevant OBP.
  - The Hub manages parallel trade reconciliation.
  - The Hub handles Multi-Market Pack (MMP) data and the market synchronisation of decommissioning. It also handles cross-border verification/decommissioning known as Inter-Market Transactions (IMT)
  - The Hub saves each OBP having to connect to each trading market individually – it's a 'single point of connection'.

EMVS OVERVIEW

- Surrounding the Hub are NMVS's – one per market.
  - The NMVS's are the systems that Wholesale, Persons Authorised to Supply (PATS) and Hospitals connect to.
  - The NMVS undertakes the verification and decommissioning activities (the Hub doesn't hold the pack data).
  - For MMP's – each NMVS informs the Hub of the transaction and the Hub synchronises the other NMVS's where the same data is held.
  - For out of market enquires, the NMVS asks the Hub to find the market from which a decommission or verification enquiry can be satisfied.
  - The NMVS also creates most of the reports required for the local NCA (some may be generated by the Hub upon request)

EMVS OVERVIEW



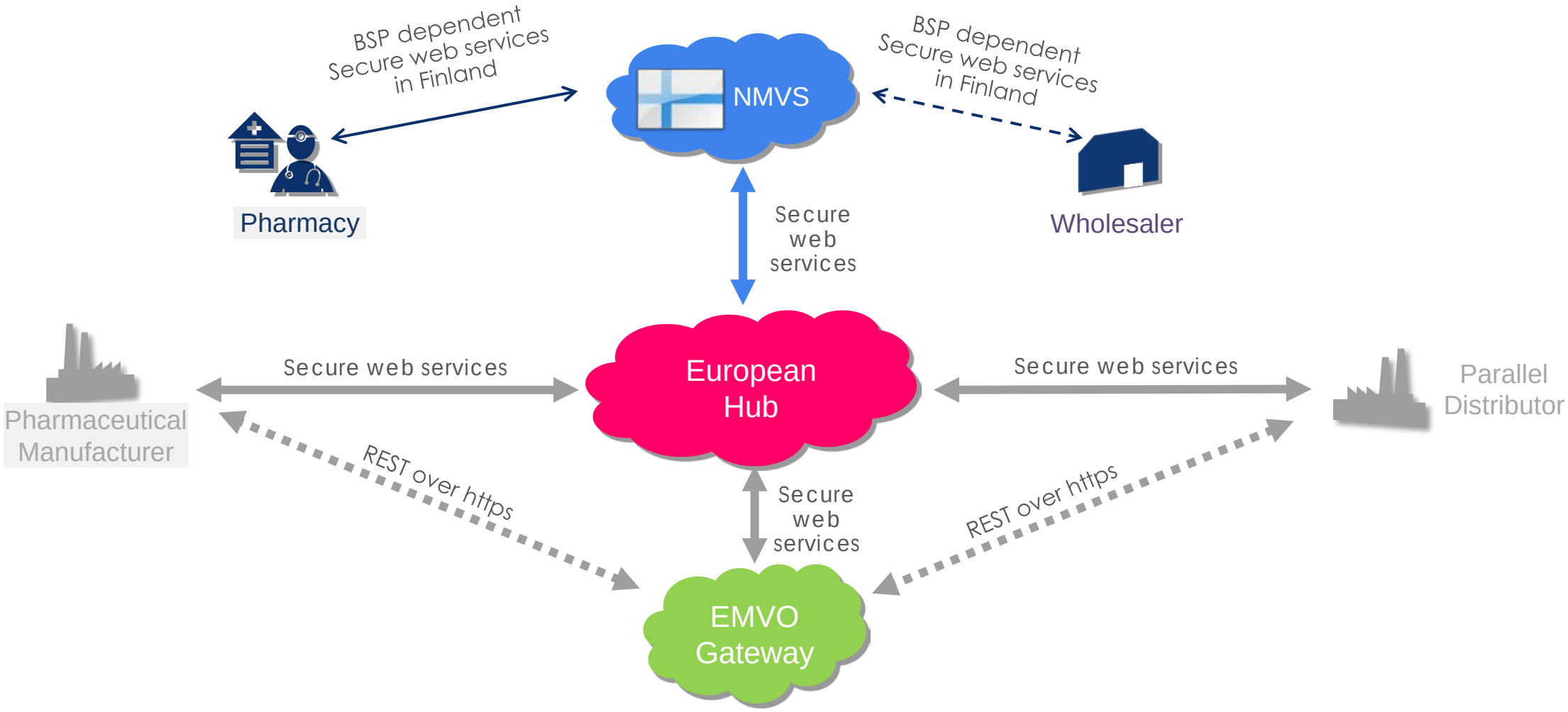
WHAT DOES THE HUB DO?

- Primarily it acts as a single point of connection for all OBP's.
- It then routes data and requests from the OBP to relevant markets and orchestrates responses and alerts.
- The Hub undertakes the responsibility for parallel distribution batch level reconciliation.
- It acts as the trigger point for batch recalls or product withdrawals.
- The Hub also provides the mechanism for allowing out of market packs to be scanned and decommissioned (Inter-Market Transactions)
- The interfaces are all secured web services
- EMVO provides a web-based Gateway system that allows easy access for OBP's during ramp-up or for continued use by smaller OBP's longer term

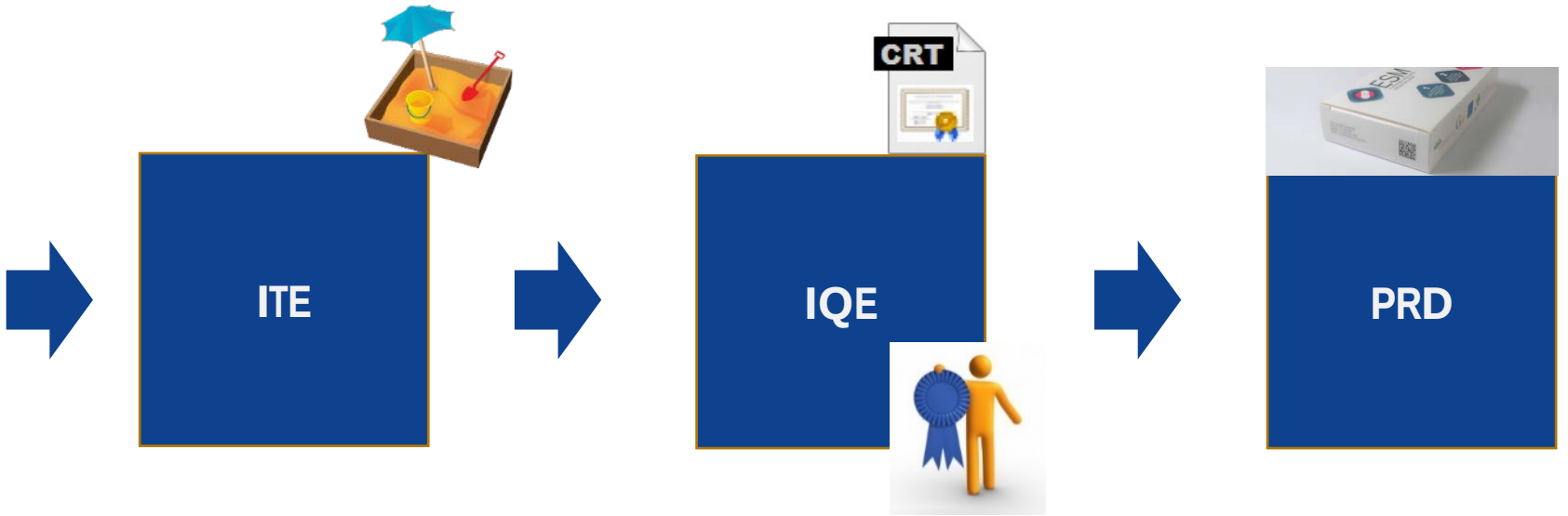
WHAT DOES THE HUB DO WITH DATA?

- The Hub:
  - Stores master data for all OBP's for all markets where the product was intended for sale.
  - It stores the batch header data for all batches or all product
  - It does not store the serial numbers nor their state.
  - It creates and manages "re-pack buffers" which are stores to manage the reconciliation of parallel distribution activities.
    - Inbound buffer for product code and batch ID decommission (and all the serial ID's) plus the total dose count decommissioned.
    - Outbound buffer for the product code and batch ID created, linked to the inbound buffer plus the serial ID's created and the total doses repacked.
  - Stores audit trails for every activity including a non-repudiation log for inbound messages.
  - Stores the required mapping data for Inter-Market Transactions and stores an audit trail for all IMT activities.

EMVS AND HUB CONNECTIVITY



EU HUB ENVIRONMENTS



ITE environment
- **I**ntegrated **T**est **E**nvironment
- Used as sandbox by multiple OBP's
- Integration testing of OBP's connection

IQE environment
- **I**ntegrated **Q**uality **E**nvironment
- Used for Quality- & Certification testing by multiple OBP's
- Validated environment

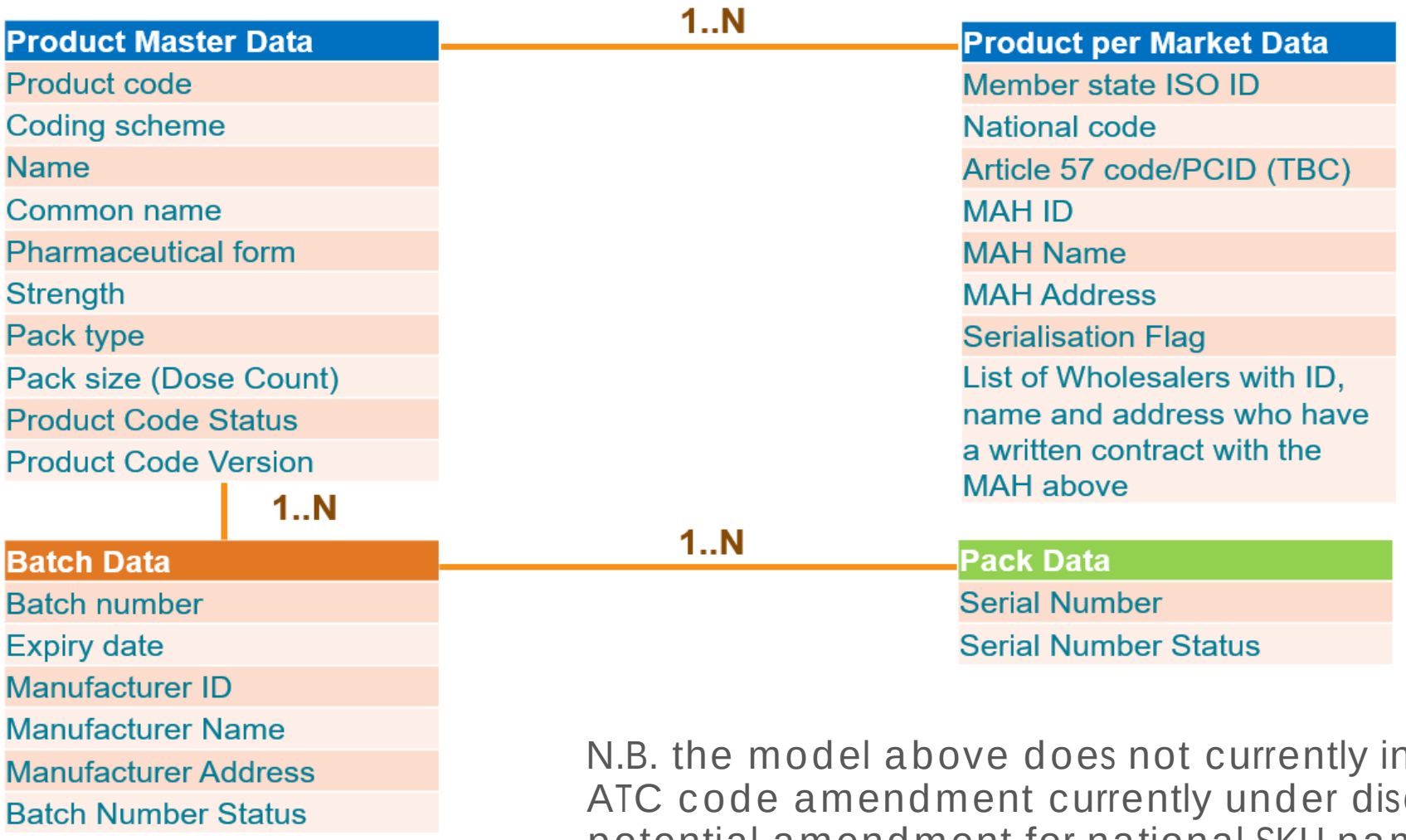
PRD environment
- Productive Environment
- Validated environment

IQE: Integration Quality Environment
IQE: Integration Quality Environment
PRD: Productive Environment

EMVS DATA

- Master Data
  - The ‘stuff’ that describes the product/SKU and that defines which markets it will be sold.
- Batch Data
  - The batch header (Batch ID and Expiry) and MFR details and the serial ID’s.
- Parallel Distribution
  - Treated as an OBP except
  - Batch data creates reconciliation stores in the Hub holding the decommissioned serial ID’s, the product and batch codes and the number of doses decommissioned
  - Newly commissioned product/packs are then linked to the stores.

EMVS DATA CONTENT



N.B. the model above does not currently include the ATC code amendment currently under discussion nor any potential amendment for national SKU naming.

EMVS DATA

- Contracted Wholesalers
  - See Article 33 (h).
  - These are the wholesalers (most likely 3PL's) with whom you have a written contract to store and distribute (note nothing is said about selling!)
  - Likely to be a very short list for most products
  - This isn't a list of all the stakeholders that handle/sell your product.
- A reasonable source of guidance regarding Master Data can be found on the EMVO website.
  - https://emvo-medicines.eu/new/wp-content/uploads/EMVO_0122_EMVS-Master-Data-Guide.pdf
  - Document due for revision to include IDMP (SPOR) mapping information and EMVO Gateway element name mapping.

MULTI-MARKET PRODUCT

- EMVS supports OBP's sending data to multiple markets in one single transaction.
- The NMVS and Hub maintain the synchronisation of packs spread across these markets
- The Hub allows for batch recall to be targeted by market (or multiple markets) for MMP's
- The Hub handles product withdrawal for MMP's in one single message (similar to batch recall).
- All responses from multiple markets are reported to the OBP in a manner that is easy to decipher.

MULTI-MARKET PRODUCT

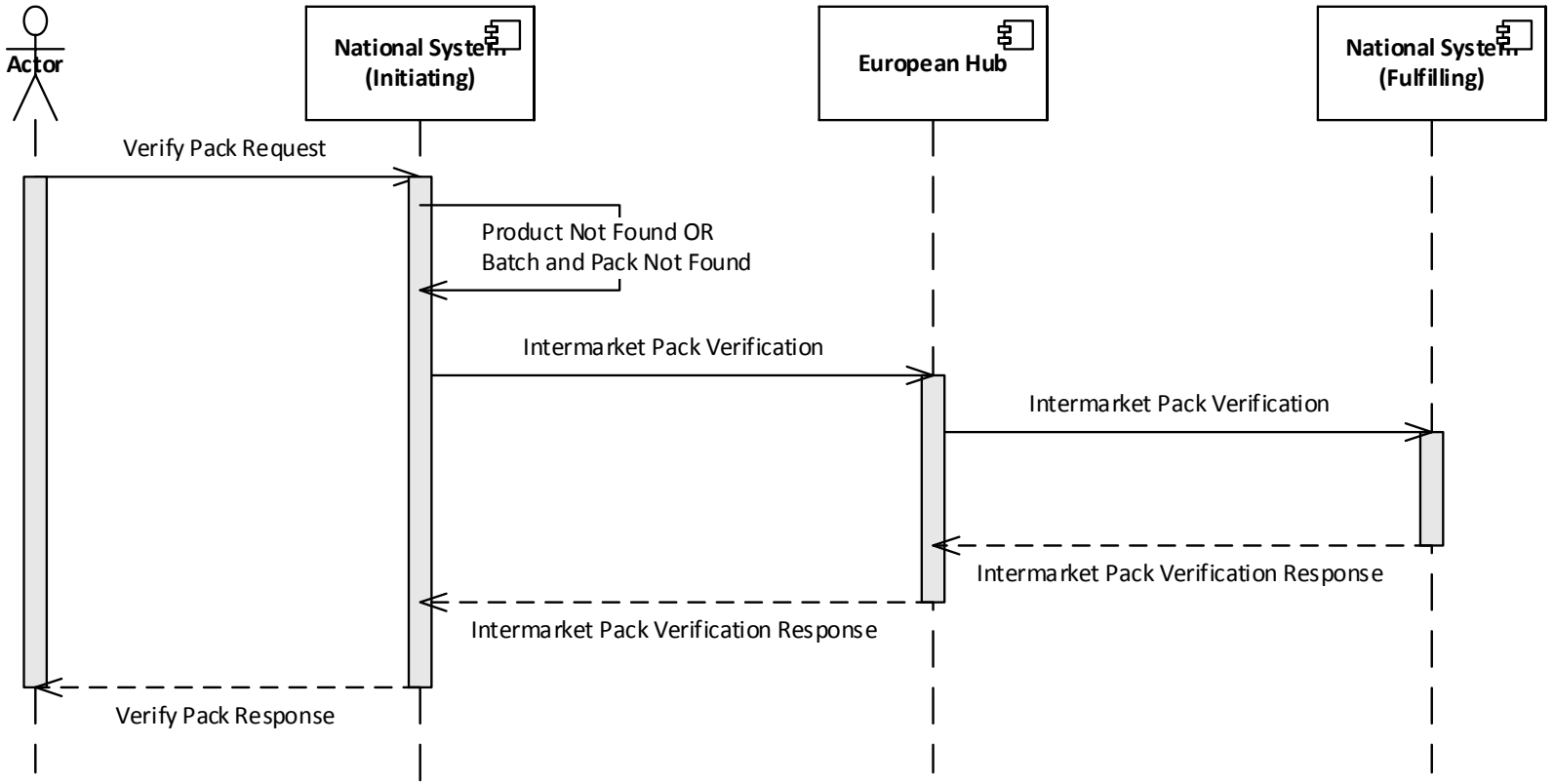
- Let's step through a three market MMP process
  - Assume the OBP has loaded the data and the Hub has sent it to all three markets.
  - A pack is decommissioned in Market A successfully
  - Market A sends a notification to the Hub that pack xyz of product abc, batch 123 has been decommissioned to a state S.
  - The Hub checks the master data for product abc, batch 123 and determines the markets of intended sale.
  - The Hub sends a decommission request to the NMVS's in markets B and C (not A because it knows that was the source)
  - Markets B and C set the pack state for pack xyz of product abc, batch 123 to S and confirm the successful update to the Hub
  - Hub confirms the update to the NMVS in market A

INTER-MARKET TRANSACTIONS

- These are transactions that are initiated when a pack is scanned in a market where it was not destined to be sold by the OBP/MAH.
- Reasons this might happen include:
  - Compassionate use (special licence) packs.
  - Packs that are legally used on a market but sourced from another (e.g. Luxembourg uses packs from BE, FR and DE in original condition.
  - Packs that really shouldn't be there!
- How does it work?

INTER-MARKET TRANSACTIONS

- IMT Data Flow (Verification Shown)

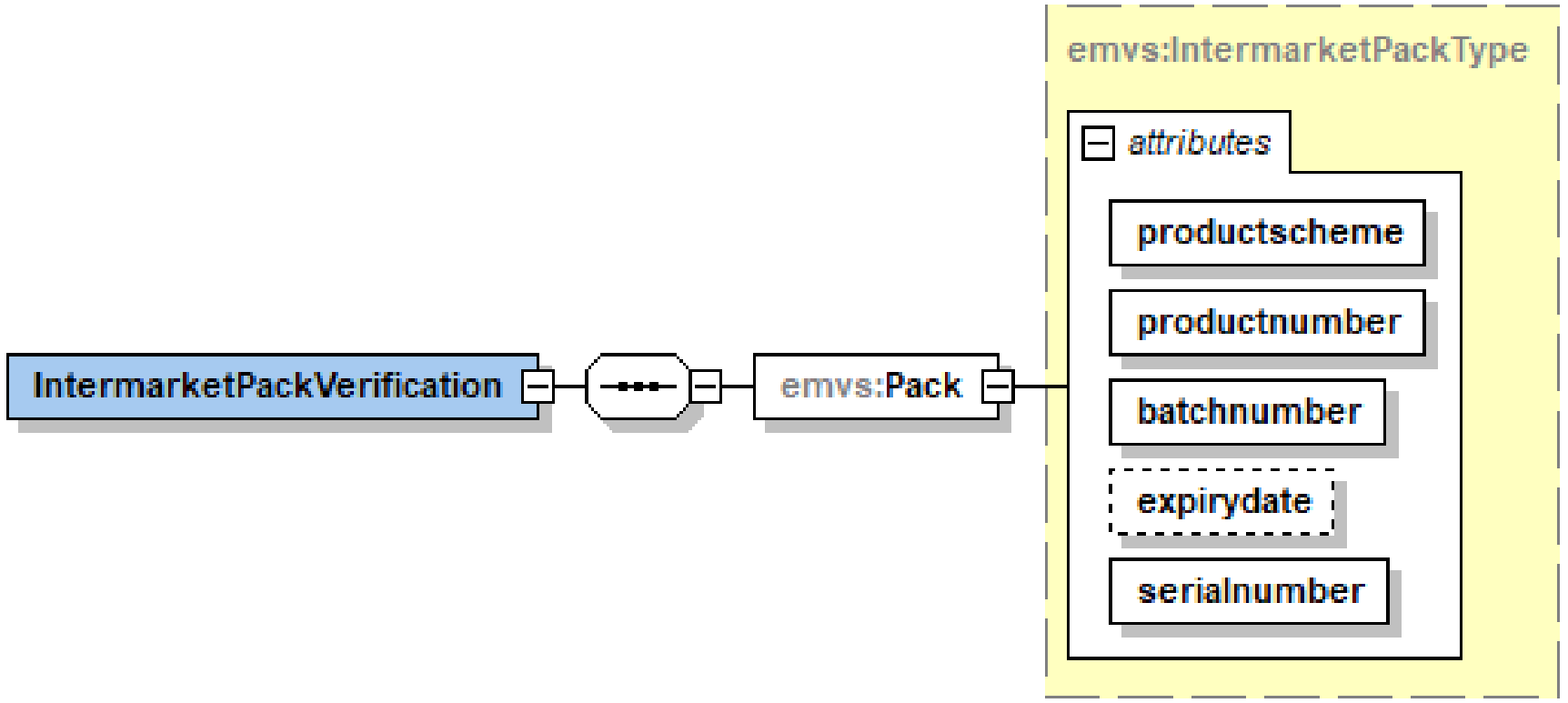


DATA TO BE SENT

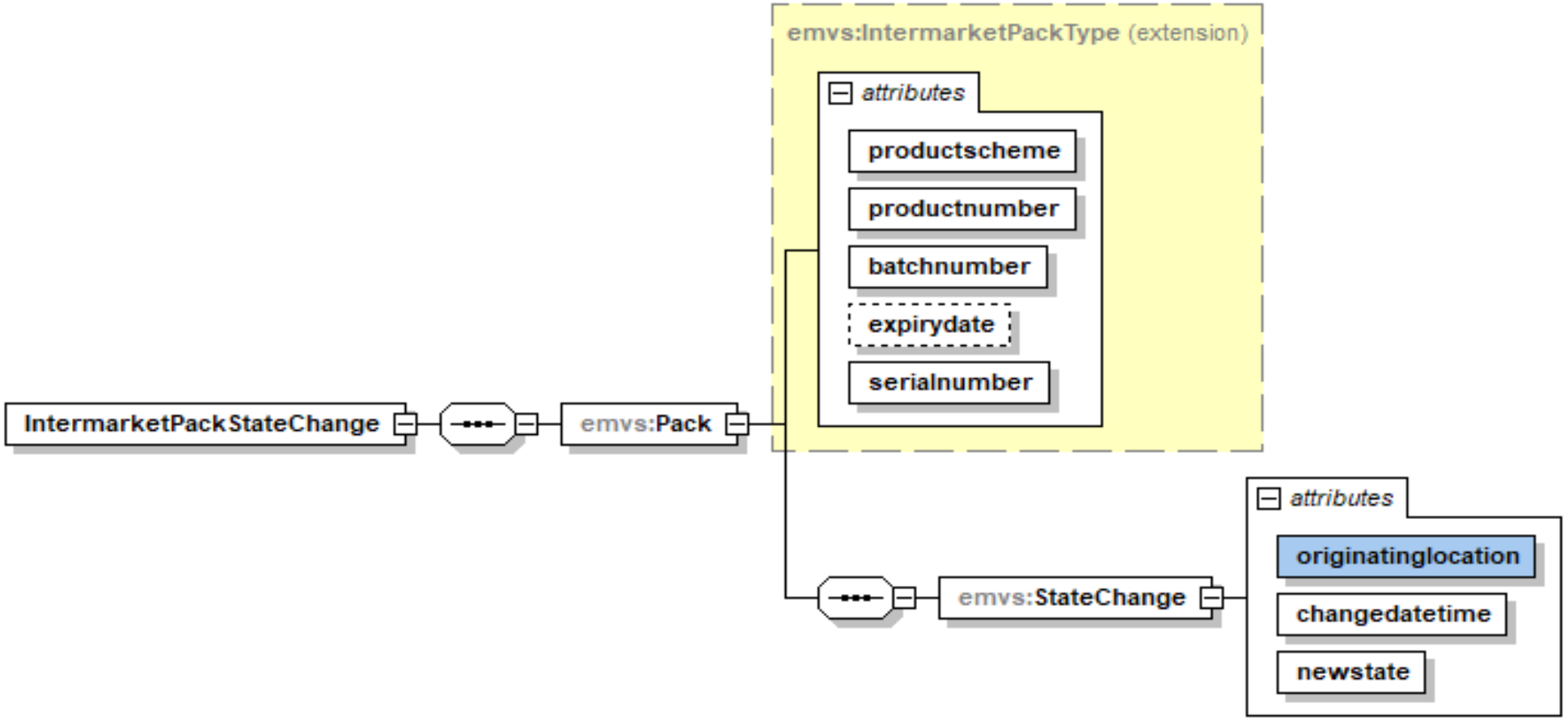
- From the initiating NMVS to the Hub and Hub to the fulfilment NMVS we need data to be sent:

  - Product Code & Product Code Scheme (mandatory)
  - Product Batch Number (mandatory)
  - Pack Serial Number (mandatory)
  - Batch Expiry Date (optional)
  - The New Pack State (mandatory)
  - The Originating Location Code (mandatory)

INTER-MARKET VERIFICATION TRANSACTION



INTER-MARKET STATE CHANGE TRANSACTION



INTER-MARKET TRANSACTION IN PRACTICE

- Now let's scan a pack the NMVS doesn't know
  - User scans a medicinal pack.
  - Details from the scan are transferred to the NMVS (national medicines verification system).
  - The NMVS "looks-up" the pack status using the data transferred.
  - The NMVS fails to find the product -> Inter-market Transaction
  - The NMVS finds the product but not the batch -> Inter-market Transaction
  - The NMVS finds the product & batch but not the pack -> the NMVS rejects the transaction, responds to the user and raises an alert.
  - Regardless of the outcome, the NMVS writes an audit log for the transaction.

IMT OUTLINE

- Inter-Market Transaction
  - Firstly – not simply a query – this includes all transaction types e.g. verification and decommission/reversion.
- Inter-Market Transaction is started by an NMVS.
  - Data from the scanned code, the transaction sought, the Client ID and Market ID are sent to the Hub.
  - The Hub checks the product master to find the product code
    - If not found – returns an error "product not found" to the NMVS.
  - The Hub checks the product master to find the batch code
    - If not found – returns an error "batch not found" to the NMVS.
  - Assuming the Product Code and Batch Code combination is found, the Hub forwards the request to a market indicated as a "market of intended sale".

IMT OUTLINE (CONTINUED)

- The "market of intended sale" NMVS receives the transaction and looks up the pack status.
- The pack status (or an error) is returned to the Hub.
- The NMVS makes an audit log record stamping the transaction with the details and the original client ID and original market ID and the date/time.
  - Why stamp with these – because the NMVS that physically undertakes the transaction requested is in control of any potential reversal operation so needs to log who and where and when.
- The Hub will receive the response and forward it back to the original NMVS where the scan occurred which in turn will inform the user.

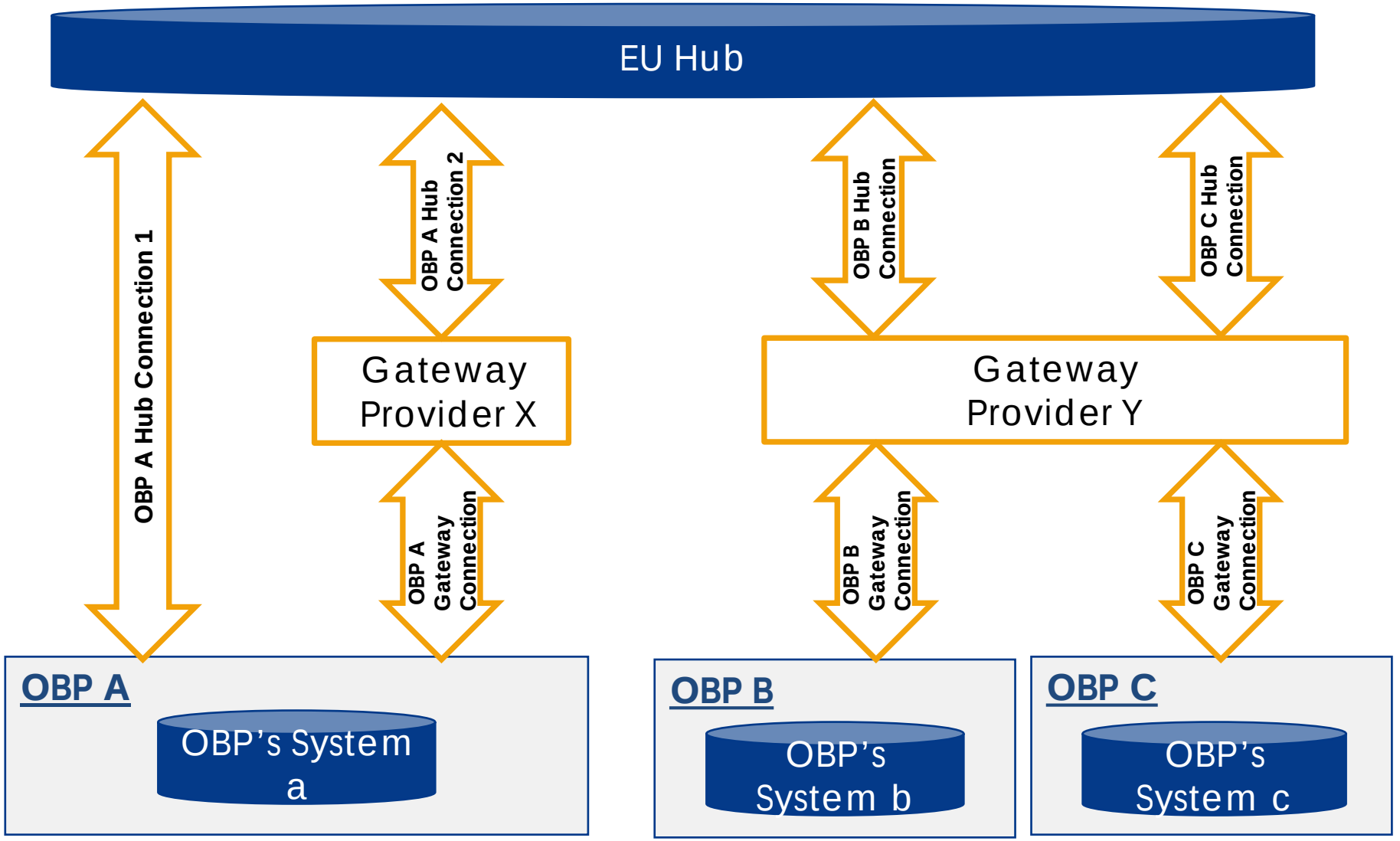
IMT REVERSAL

- The same process as the original transaction but:
  - The NMVS for the "market of intended sale" will now check that the criteria defined in Delegated Regulation Article 13 specifically:
    - Reversed within 10 days following the original decommission
    - Pack has not expired or been placed under recall, withdrawn, destroyed or stolen and;
    - The reversal is performed by a person within the same premises as the person who originally decommissioned the pack (unique identifier)
  - As such it is vital that the NMVS which undertook the original decommission knows who undertook the original decommission (i.e. the Client ID and Market ID combination) and when they did it.

OBP CONNECTIONS

- When onboarding OBP's have the choice of direct connections or gateway connections,
- Direct
  - These are connections made directly from an in-house/on-premise system like an ERP or stock management system. e.g. SAP ATTP.
  - These connections rely on the provider configuring the system to work for the client and not using a common connection provision.
- Gateway
  - Here the system supplier is providing a common service to many OBP's and in general, these systems are not on-premise but cloud-based.
  - Examples would include the EMVO Gateway, Tracelink etc.
  - The key is that the connection used to the Hub is 'common' to all OBP's using the system suppliers product and thus, EMVO have a higher expectation that the connection is reliable and unchanged from last use.

CONNECTION TYPES

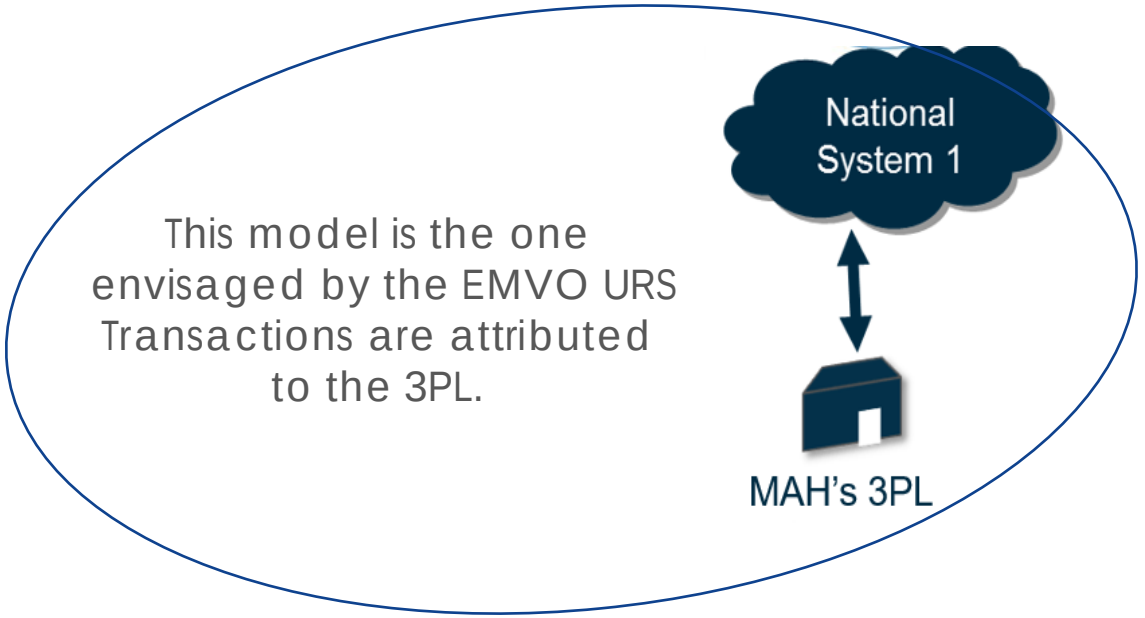


RETROSPECTIVE DATA UPLOADING

- Only important for multi-market product or if serialised product is placed on a market before the NMVS is live and productive.
- The idea here is to upload data for serialised product as the sales market(s) come online potentially after physical product has been shipped and consumed.
- As an OBP you do this to:
  - Make the serialised product data available in the NMVS where you sell.
  - To avoid being deluged with false negative alerts (which will happen if the product data doesn't exist – the EMVS will consider your packs as potentially falsified.
- Retrospectively uploaded data will, by definition, have pack status indications that are wrong – because stock will have been used before being decommissioned.

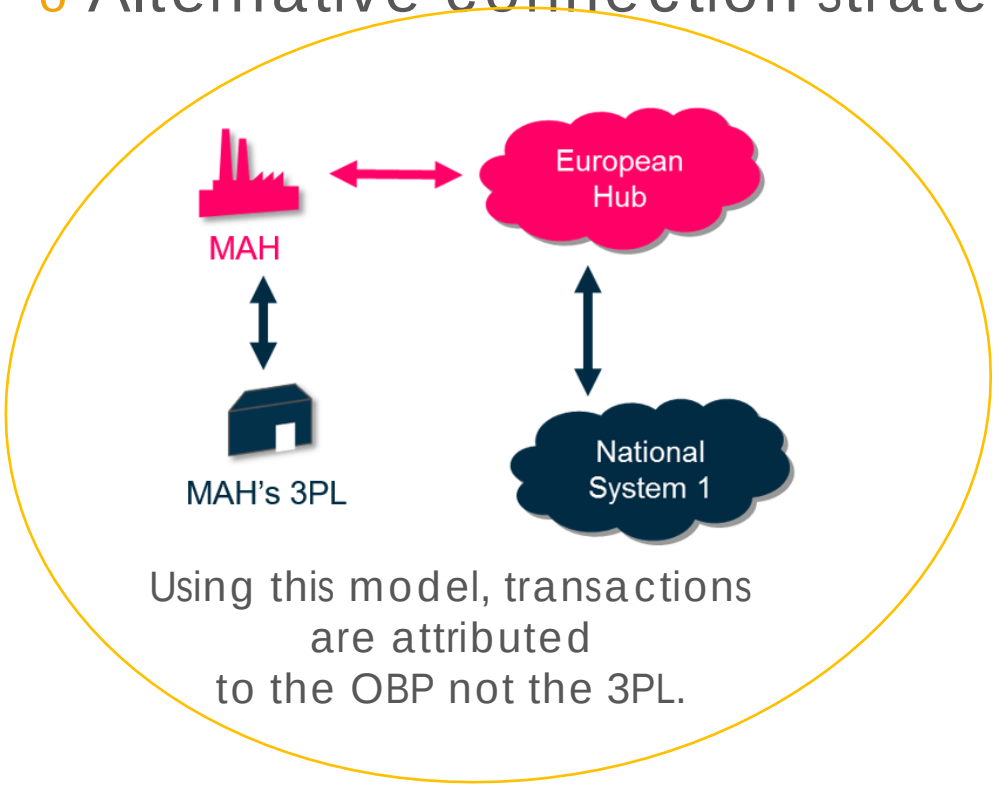
WHOLESALE – 3PL'S

- Wholesalers and 3PL's connect to the NMVS and not the Hub at least that's how the URS envisaged it.

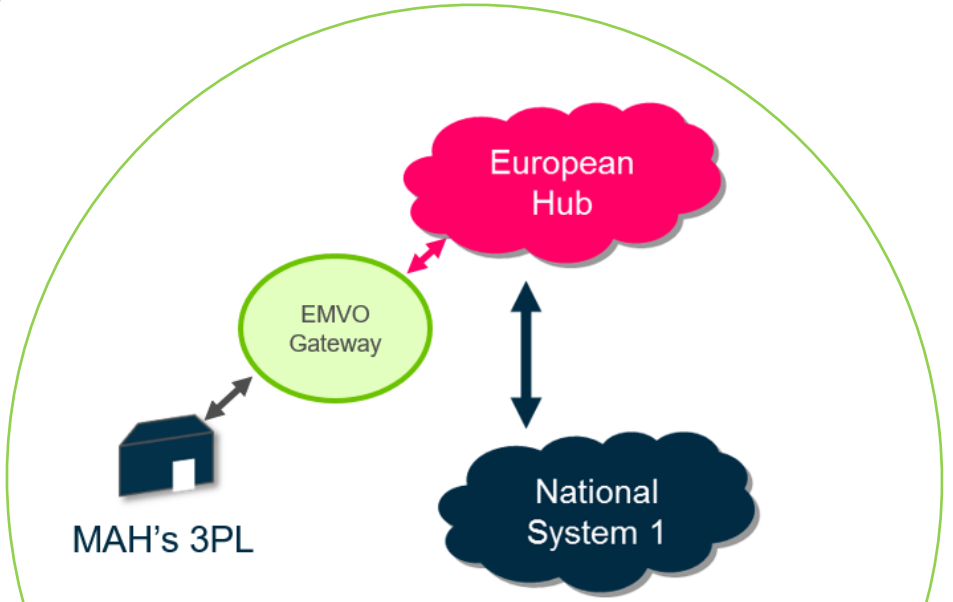


WHOLESALE – 3PL'S

- Alternative connection strategies include:



Using this model, transactions are attributed to the OBP not the 3PL.



This model is low cost to deploy but may be more costly for the 3PL to operate. This one does mark transaction as undertaken by the OBP