

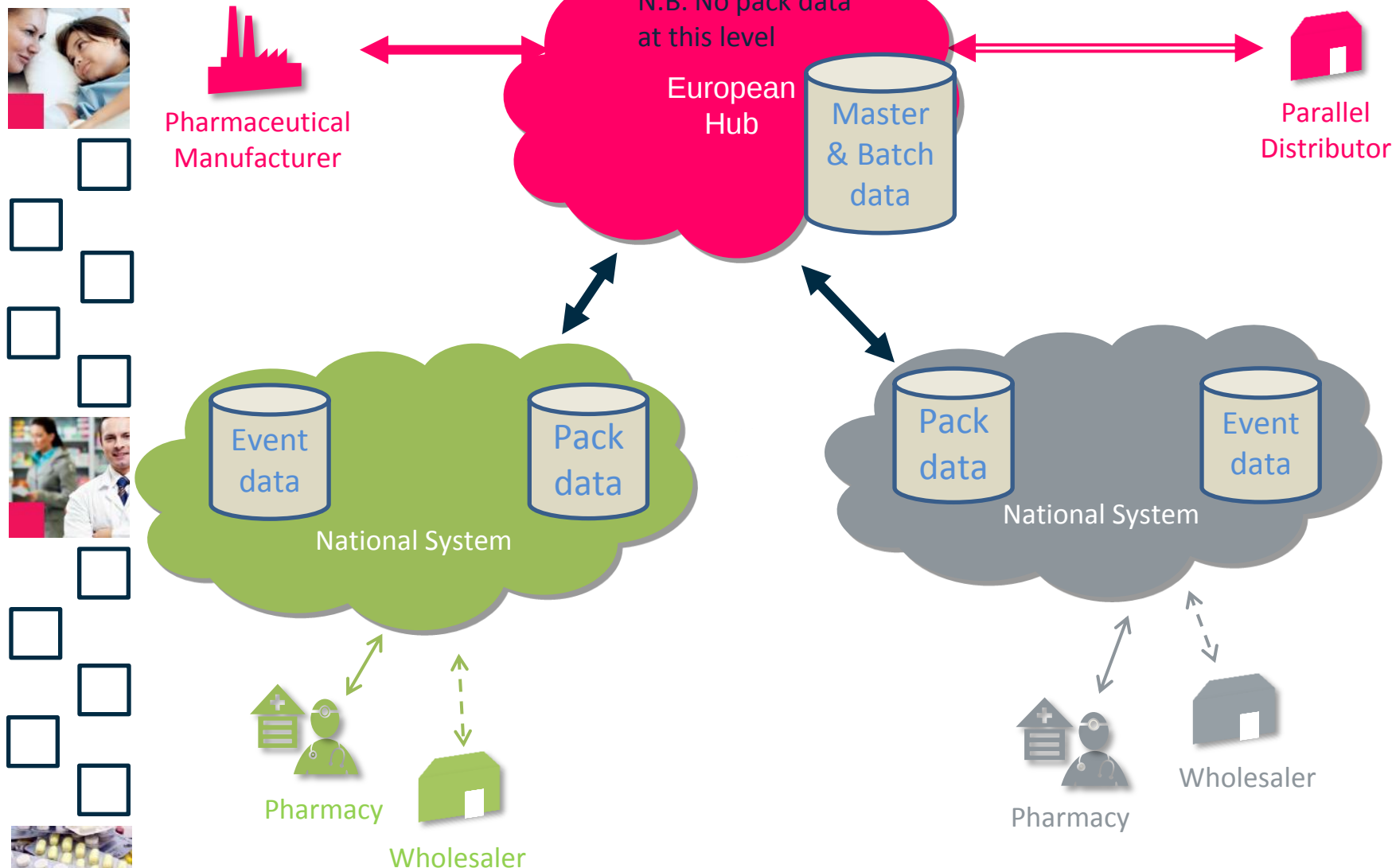


European Hub Introduction and Data Set Requirements

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European Hub and the EMVS



What is the European Hub



- ☐ It's a centralised data moving system– like a switch.
- ☐ It allows all MAH's to connect to one single entity and then...
 - It distributes data from MAH to National Systems.
 - It distributes alerts from National Systems to EMVO and when appropriate, to MAH.
- ☐ It provides basic reporting tools.
- ☐ It allows multi-market product to be synchronised between markets.
- ☐ It provides a parallel trade/distribution reconciliation function.
- ☐ It makes the European Verification System easier to implement.



What the European Hub is NOT



- ❑ It is NOT a central European Master Data repository.

- There's simply too little data held to make this realistic.

- ❑ It is NOT a central register of all medicinal packs on the market.

- Pack level data is abstracted to the National Level.

- The Hub does not retain pack data after distribution.

- ❑ It is NOT a verification system

- It needs National Systems to provide the Verification aspects.





- ❑ The principle adopted when designing the requirements for the Hub was to minimise the data held/required.
 - It holds small amounts of Master Data (to allow it to function)
 - It holds all the batch header information for all products as batches are introduced to market
 - Importantly it holds no pack level data.
 - It holds some Organisational Data – to identify the client.
- ❑ It currently sources all data from MAH's as there is no practical alternative...yet?!
- ❑ Ideally the Hub would obtain data from a central reliable and accurate source.



☐ Product Code

- Product Code Scheme (GTIN (GS1) or PPN (IFA))



☐ Alternative Product Codes <List>

- Alt. Product Coding Schemes (as above)



☐ Product Name



☐ Dose Count (*Doses in the Pack*)



☐ Strength

☐ Dose Form

☐ Pack Type

☐ Target Markets <List>

☐ Effectivity Date

☐ Batch Code <List>

- Batch Expiry Date



Note: This model is expected to change a little when the content of the Delegated Acts is made public.

We expect to remove the highlighted fields when we amend the model.