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Implementation of FMD in hospital care

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Problem statement

- Volume of prescriptions dispensed through hospitals is about 10% of the total volume of packs in Europe, i.e. > 1 bn packs
- The supply chain shows big variations across Europe both in buying and distribution. This means different levels of risk and sometimes lack of understanding of the requirements.
- There is a lack of infrastructure for decommissioning in many hospitals:
  - Big variations in IT software – skills and resources are needed urgently.
  - Scanning is often not a part of the routine and is seen to add to the workload – need additional resources, training etc.

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Features of a solution

- Align with security objectives of the FMD
- Decommissioning is done when the pack is in the physical possession of the healthcare institution – but as far back in the chain as possible.
- Be accepted by the EMVO and NMVOs
- Be implementable within the existing timelines (allowing for any additional work which may need to be undertaken by stakeholders)
- Be cost effective, practicable and clearly identify likely costs and accountability for these

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Learnings

- A waiver is not an option.
- Aggregation is not a solution *per se* – verification/decommissioning capabilities and connection to the National system must be implemented. Aggregation functionality is not part of the EMVS.
- Point of administration capability is being developed further for vaccines decommissioning. This work could be useful for many healthcare institutions.
- There is not one solution that will fit all.

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Manual/Semi automated decommissioning

The ability to process higher volumes of packs (without aggregation) which are often temperature sensitive, in order to fulfil an order.

- Solutions to scan and process serialised product in a supply chain environment already exists (above examples – UAE and Argentina) e.g. hand scan, verification table.
- Solution would connect to the NMVS via existing IT systems in place to carry out other FMD operations e.g. Returns
- Will operate with existing E/NMVS functionality
- Processing cost implications?

Point of administration capability

Mobile devices enabled to authenticate the safety feature at the point of administration (similar to a device use to track a parcel delivery).

- Multiple mobile solutions could be available to meet the needs of the variety of different dispensing operations
- Solutions would be developed and sold by solution providers
- The mobile solution would communicate with an NMVS and the users organisation onboarded accordingly
- The capability to link into the NMVS and the administration method to onboard would have to be established

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Connection to national system is required

- Contractual on-boarding of end-users to the National system
  - Apply for a connection and conduct legitimacy check
  - Sign a contract with the NMVO (content prescribed in the EMVO-NMVO contract)
- Technical on-boarding
  - *(Agree changes in the current IT system based on changes in the workflow)*
  - Hospital system IT-provider obtains information to set up the interface and connect to the ITE for the National system, performs testing and finally is certified in the IQE environment.
- Once completed, the system can be connected to the live environment, the end-user obtains credentials via the NMVO and can log in.

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Possible solutions to explore

1. Change management – engagement phase; look at benefits to hospitals beyond FMD?
2. Can we engage key hospitals to pave the way?
   - Hospitals will have to adapt their processes: best practice sharing?

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Thank you!

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