Belgian Association of Hospital Pharmacists
Detailed TraceLink Engagement Proposal

Protect Patients ● Enable Health ● Grow Profits ● Ensure Compliance

10 October 2017
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1. TraceLink FMD Hospital Compliance Service

The TraceLink FMD Hospital Compliance Service will provide Belgian Hospitals with a comprehensive service to connect individual hospitals to the local Belgian National System and enable the transmission of each of the transaction types required by the regulation. In addition the TraceLink service will provide the opportunity for the hospital to receive other important supply chain or patient safety information from the manufacturer if both parties agree to connect and exchange permissioned information with each other. Other TraceLink benefits include a variety of different reporting functions, aggregation and the ability to support centralised dispensing and unit dose processes.

The TraceLink FMD Hospital Compliance Service is available in different connection formats depending upon the needs of the individual hospital.

Hospitals represent a specific challenge given that the Delegated Regulation provides the flexibility that medicines decommissioning can be completed at any point where the medicine is within the physical control of the hospital. Whilst this may appear to provide the hospital with more flexibility, the practical impact is that each hospital needs to have a detailed understanding of their supply chain to be able to make a decision as to the optimal location to decommission. Invariably, flows of medicines are different in each hospital and as such a single recommended approach would not necessarily provide the optimum solution.
2. TraceLink Engagement Benefits

The TraceLink Life Sciences Cloud Network connects manufacturers, contract manufacturers, wholesalers, repackaging companies and retail and hospital pharmacies together on a single network platform, which also interfaces with the Belgian National Blueprint Service. These connections not only facilitate FMD compliance but also enable network users to share other information on a dual opt-in, permissioned basis. The best example of this is serialized aggregated pack data which cannot be uploaded to the European Hub or National System, but can be communicated and used via the TraceLink Network.

A key aspect of TraceLink’s offering is in its delivery of a GxP-validated, GAMP-aligned FMD Compliance Service. This is important as there will now be quality decisions made about the individual medicines based upon the scan and the response from the national repository. When the manufacturers, the EU Hub and the national systems are all GAMP-aligned – it makes very little sense to endanger the entire system by connecting to a non-GAMP service to complete the final step in the chain.

TraceLink’s track-and-trace compliance knowledge and experience gained with more than 700 customers in multiple geographic markets provides the Belgian hospital association with the confidence that the service can be delivered on time and in-full. This expertise also means that TraceLink already can provide services to meet specific dispensing use cases such as centralised dispensing. Aggregation and the ability to decommission multiple serial numbers with one scan of the shipper box has already been identified as a benefit by the hospital association and TraceLink’s strong manufacturer base is a positive attribute for the association. Currently, TraceLink has European-wide serialization contracts with 55 pharmaceutical manufacturers.

In addition to this, TraceLink can also support decommissioning of medicines which are subsequently split into unit-doses, where a relationship and audit trail between the parent pack and the unit dose is beneficial to establish.

TraceLink’s established service also provides for full reporting to be provided to individual hospitals and this is also aligned to the reports generated for the NCA within the National System.

3. Belgian Market

The Belgian National Medicines Verification Organisation (BeMVO) has been formed and Arvato appointed as a service provider.

The Belgian Association of Hospital Pharmacists are now looking to understand how their members can become compliant with the FMD and understand the impact on the medicines supply chain within hospital. The association has already completed an initial feasibility study, which based upon purely the time to scan medicines, would they believe require an additional 200 staff within all Belgian hospitals. The hospital pharmacy association has also informed TraceLink that 97% of all prescription medicines come directly from the manufacturer.
4. TraceLink’s Unique Product Offering for Belgian Hospitals

TraceLink’s EU FMD Compliance Service represents a unique offering for Belgian Hospitals. The combination of manufacturers serialised codes and aggregated information already held on the TraceLink Network, the ability to work with centralised dispensing and unit dose delivery, mean that together with the connection to the National System, TraceLink are able to offer a unique service to Belgian Hospitals that is not available from any other supplier.

5. Product Description

The TraceLink FMD Compliance Service consists of the following elements.

4.1. Connection from the hospital pharmacy to the local National System (repository) – via Mobile, stand alone or API interface
4.2. Ability to exchange serialized data between Hospitals, distributors, wholesalers and manufacturers and to provide medicine verification and decommissioning via the Belgian National Blueprint System
4.3. Responses on the product status and successful decommissioning of the medicine as per the functionality required by the FMD and defined by EMVO.
4.4. Ability to provide additional content and information to pharmacy (content supplied from manufacturers)
4.5. Alignment with EMVO and NMVO requirements
4.6. Authentication of system users
4.7. Ability to work with centralized dispensing capability (Hub and Spoke)
4.8. Ability to function in an offline mode if internet connectivity is lost (via mobile application).
4.9. Ability to decommission multiple aggregated serial codes at goods in, via the TraceLink network with participating manufacturers and wholesalers
4.10. Work with wholesalers to facilitate decommissioning for hospitals
4.11. Decommissioning and subsequent linking to unit dose identifier either within hospital or at a third party location
4.12. Full reporting and audit functionality

6. Belgium Hospital Association Scope of Work

The scope of work has been split into two areas, with the first being the pilot activity, and the second being the implementation across the remaining hospital association membership based upon the completion of a successful pilot.

7. Pilot Detail

It is intended to run a pilot in one Belgian Hospital to provide a demonstration of TraceLink’s service and to discover/resolve any potential connection or hospital workflow issues that may exist. TraceLink will work with the pilot hospital to identify the optimum location for decommissioning to take place. Initially it may be beneficial to run the pilot using a stand-alone service, or to compare a stand-alone versus an integrated service as part of the pilot either in the same hospital or at second hospital location. It is intended that the pilot pharmacy chosen will operate with standard requirements and functionality in order that it can represent the basic compliance needs of the FMD.
8. Pilot Implementation

The pilot implementation will be completed by TraceLink’s Services Team. The pilot will include several communication and knowledge sharing events to ensure all personnel impacted by the pilot have the necessary knowledge to complete the pilot activities. Detailed implementation information regarding the project activity will be communicated in advance by TraceLink to the pilot hospital. This will also include three local workshops to complete discovery activity with the pilot hospital, to ensure alignment on pilot activity, and to prepare for the pilot’s implementation.

There are a number of dependencies and activities required to be able to support a Belgian hospital pilot, these are:

- Receipt of a copy of the Belgian interface specification from Arvato
- TraceLink connection to the Belgian National System
- Finalised pilot agreement with the Hospital Pharmacy Association
- Selection of the pilot hospital
- Completion of a workflow analysis within the pilot hospital to agree verification/decommissioning points.
- Decision as to the interface specification required (mobile or integrated)
- Implementation of the chosen TraceLink interface within the pilot hospital
- Changes to hospital procedures to facilitate the scanning and subsequent activity based upon responses from the National System
- Provision of pilot training materials
- Availability of 2D serialised codes within the Belgian National System to test responses within the pilot study period

9. Pilot Success Criteria

Pilot success criteria will be based up on being able to complete all transaction types associated with both the verification and the decommissioning of medicines, together with any reporting requirements from the National System. In addition to this the pilot will record National System response times and performance to agreed service levels and KPI’s.

Pilot Transaction Types

The following transaction types will be tested during the pilot period.

- Verify Pack
- Dispense (Decommission) Pack
- Re-introduce Dispensed Pack
- Decommission Pack
- Undo Decommission Pack
- Request Report

In addition to this packs with specific error flags will be introduced into the hospital pharmacy. These packs will be authentic product (so if they are not caught and flagged there will be no negative patient impact), but they will be used to test the efficacy of the service and the ability of users to remove ‘problem’ packs from the supply chain. These ‘problem’ packs will take the form of:-
Pilot Problem Packs
- Expired Packs
- Already Decommissioned Packs in Pilot Hospital
- Recalled Packs
- Suspect Packs (Previously Decommissioned Pack Identities)

At the start of the pilot there will be an assessment made of the knowledge and understanding of the system users regarding the FMD and their role. This assessment will be completed at the end of the pilot to understand if the knowledge and understanding of the FMD and hospital process has altered during the pilot. The questionnaire at the end of the pilot will also focus on users’ learnings and any recommendations that will effect a more efficient association-wide roll-out.

Pilot Success Criteria
During the pilot it is expected that 100% of all serialised 2D codes presented to the TraceLink service will be transmitted to the Belgian National System. TraceLink will record and display 100% of all messages returned from the Belgian National System. It is expected that 100% of all highlighted ‘problem’ packs presented to the TraceLink service will be read successfully and the corresponding message displayed. TraceLink will analyse the number of problem packs presented against the number in the pilot to determine if any medicines were dispensed without being scanned. As part of the pilot activity TraceLink will work with the hospital to determine what the actual impact is of decommissioning medicines within the hospital environment.

Response Times
Response times both of the Belgian Blueprint service and the TraceLink connector will be collected and reported during the pilot period. Assessment will be made regarding the performance of the Blueprint service to the Delegated Regulation KPI response time of 300ms. Overall decommissioning times will also be established.

10. Market Implementation
Following a successful pilot TraceLink will work with Belgian hospitals to complete a roll-out to all locations. TraceLink will work with the Belgian Hospital Association to ensure the communication of requirements, implementation timelines and overall project management objectives. TraceLink will validate hospital connections, provide user logins and certify each hospital in the live FMD service.

For the market roll-out to be completed by TraceLink there are a number of additional dependencies. These are:-

- Comprehensive list of all Belgian hospital locations who will have to connect to the National System will be required by TraceLink
- List of key contact personnel at each hospital location
- Agreement by the Belgian Hospital Pharmacy Association to a communication plan by which implementation process can be communicated
- Agreement on the on-boarding process for each hospital
- List of solution implementation options for each hospital location
- Support from existing software system providers if the decision is made by the hospital to request an integrated approach to the decommissioning process
11. Delivery
The successful delivery of the services will be measured by the scanning of medicines in each participating hospital and the subsequent receipt of the correct response from the National System. Additional success metrics will be jointly determined by the hospital association, the pilot hospital, and TraceLink prior to pilot commencement.

12. Timelines
It is anticipated that a pilot would run for three months followed by a roll-out to other hospital pharmacies. Exact timing will be dependent upon the operation of the Belgian National System and TraceLink would work with the BeMVO regarding timing of the pilot.

13. Risk and Risk Mitigation
Regular project meetings will occur during the pilot and implementation period. A key aspect of these meetings will be to focus on the risks and mitigation activity.

14. Association Benefits
In addition to the comprehensive FMD service offering that TraceLink is able to provide the Association, TraceLink can also provide a commercial agreement which reflects favourable aggregated pricing based upon the commitment of the entire Belgian hospital market. The ability to benefit from operational efficiencies mean that TraceLink can provide a win-win approach for all parties and deliver a unique service offering to Belgian Hospitals.