MEDICINE VERIFICATION:

THE COSTS AND SERVICE BENEFITS FOR THE PHARMACEUTICAL INDUSTRY OF A ‘SINGLE END-TO-END SERVICE’ VERSUS ‘A MULTIPLE PROVIDER SERVICE’

Executive Summary

This paper details the impact on the pharmaceutical industry of two different approaches to the delivery of medicine verification service required by the EU Falsified Medicines Directive. The two approaches – ‘Single End-to End Service’ and ‘Multiple Provider Service’ – can be best differentiated by comparing where the responsibility for the verification service provider ends, as well as the number of different providers engaged in the delivery of the service. Each of these approaches has significant cost, performance and service issues, with a corresponding impact on manufacturers (as the group identified to pay for such a system).

‘Single End-to-End Service’. In this approach, one service provider is responsible for providing a complete medicine verification service. Here the service provider takes responsibility for the entire service, for the verification of each medicine pack from the time that the medicine is scanned in either a dispensary or a wholesaler to the processing of the response in the database and the display of the pack status to the dispensary or wholesaler. A critical differentiator of this service is the integration of the medicine verification service, through an encrypted software library placed directly into the patient medication record software at the dispensing point, or the inventory control software at the wholesaler.

‘Multiple Provider Service’. In this approach, while one service provider is responsible for the central verification database, multiple third party software providers are needed to interface with the central verification database. Consequently, the verification of each medicine pack is handled by at least two providers and there are at least two handover events: one from when the medicine is scanned in either a dispensary or a wholesaler, and then handed over to the central database; the other after the response is processed in the database and the subsequent pack status is handed back to the software at the originating dispensary or wholesaler.

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This paper highlights the differences between these two approaches and shows that the most cost effective for the pharmaceutical industry is a ‘Single End-to-End Service’. A further benefit is that this approach closely aligns with what is believed to be published in the Delegated Acts (DA). Additional value added can also be generated through the service offerings that only a network structured around a ‘Single End-to-End Service’ makes possible.

**Single End to End Service**

The ‘Single End-to-End Service’ is one where the service provider takes full responsibility for the entire ‘round trip’ of the journey of each medicine that is verified using the system.

The key advantages of this approach are:-

- **Response Time**: The service provider can measure the complete end-to-end ‘round trip’ response time for each transaction. This is critical to ensuring that users are not delayed and service levels can be monitored and maintained. The DA are believed to highlight the need to provide a verification service which will meet a 300 millisecond end-to-end response time. As such, response times will need to be monitored closely.

- **Cost**: Under a ‘Single End-to-End Service’, the cost of integrating into multiple patient medication record systems is actually lower than the equivalent cost of providing separate interface specifications in the ‘Multiple Service Provider’ approach and dealing with the software interface problems this entails. This is due to the standard software agent placed seamlessly into the existing PMR systems.

- **Security**: The security of the ‘Single End-to-End Service’ is far higher than that experienced with a ‘Multiple Service Provider’. Additional security can be embedded into the software used by the service provider. This approach has the ability to ‘abstract’ the security interface and handle it inside the service providers code, without exposing the security logic to external interfaces.

- **Continuity**: A ‘Single End-to-End Service’ is less exposed to software changes within the individual patient medication record software – these generally suffer from frequent release changes. This results in a more robust service which benefits all users and avoids the situation where the system may well be down through an error made by a third party software provider.
• **Standardisation:** The ‘Single End-to-End Service’ approach provides a standardised Graphical User Interface which can be used to generate alert messaging across heterogeneous software applications, lowering the training costs of users and standardising the alerts across multiple Pharmacy and Wholesale systems.

• **Support:** The ‘Single End-to-End Service’ approach allows for the centralised administration of support services to all connected devices, reducing help desk calls and allowing the system to monitor service levels. The integration within the patient medication software also allows for the easy identification of the patient in the event that a serious recall is initiated. That can only be initiated by the pharmacist thus ensuring patient anonymity to the service provider.

Apart from needing a service provider who has the necessary experience, expertise and capability to interface and integrate with numerous patient medication software companies in a market, there are no disadvantages to this approach.

**Multiple Provider Service**

The ‘Multiple Provider Service’ approach is one where there is a single service provider for the verification database. However, connection to this database is reliant on individual software companies, each of which provide different dispensing software services and wholesaling services. As a result in this approach, there could easily be over ten different companies delivering medicines verification alerts and messages in a single market. This approach has a number of disadvantages:-

• **Response Time:** In a ‘Multiple Provider Service’ approach there is no practical way of measuring the complete end-to-end response time for each transaction. This means users can be delayed and be discouraged from operating the service as response time increases, without a centralised knowledge or monitoring of the service levels.

• **Cost:** Costs are higher when you need to rely on multiple third parties to write, test and implement the software required to interface with the verification database. These increased costs are a function of longer process times and may be prone to delay if individual software companies fail to perform as promised. Delays of this nature coupled with the subsequent software issues all add cost to the operator of the verification database.

• **Security:** The security of the ‘Multiple Provider Service’ approach is increasingly compromised as more software companies interface to the verification service.

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• **Continuity:** The ‘Multiple Provider Service’ approach relies very heavily on the technical, process and project management capabilities of each individual company interfacing to the verification database. Here errors are often made which will then have a negative impact on the service operation.

• **Standardisation:** There is no standard approach across different software applications.

• **Support:** The ‘Multiple Provider Service’ approach increases the complexity of the support operation to users. In these cases, a user may well direct their questions directly to the manufacturer due to the uncertainty of knowing who can answer their question. In the event that a suspicious item is found, different service providers will have different approaches to resolution. This can also increase the burden on the manufacturer.

• **Hidden Costs:** Without a single point of issue resolution, the service delivered by a Multiple Provider Service will not be able to address any remedy to either systemic issues or temporary faults since it lacks the required visibility. This will multiply the costs to the NMVOs, the EMVO and every pharmaceutical company. Likewise the National Regulators will experience a much increased workload.

Additionally the ‘Multiple Provider Service’ approach may not be aligned with the service levels expected to be contained in the DA. Certainly the need to measure and show ‘round trip’ response time performance of 300 milliseconds would be impossible with this approach, and the ability to precisely target recalls will be severely compromised.

**Conclusion**

The ‘Single End to End Service’ approach to the Medicine Verification System reduces drastically the time and costs for the service provider to implement and run the service compared to a ‘Multiple Provider Service’ approach.

In addition, it significantly reduces complexity, and requires less support from pharmaceutical companies, the National Medicine Verification Organisations and the national regulators.
# SERVICE MODEL COMPARISON MATRIX

<table>
<thead>
<tr>
<th>KEY INDICATORS</th>
<th>END TO END SERVICE PROVIDER</th>
<th>MULTIPLE PROVIDER SERVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SERVICE INTEGRATION: Efforts required for the deployment of the service and consistency in its execution</td>
<td>Effort (Man Weeks): X Time (Weeks): Y</td>
<td>Effort (Man Weeks): 10 X Time (Weeks): 6 Y</td>
</tr>
<tr>
<td>TOTAL SECURITY: Control and assurance of service security throughout all the elements of the service</td>
<td>Guaranteed: close loop</td>
<td>Not Available: Open Loop</td>
</tr>
<tr>
<td>SUPPORT:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Ensuring service availability</td>
<td>1) Measured availability:99.998%</td>
<td>1) Not measurable, compounded by multiple suppliers</td>
</tr>
<tr>
<td>2) Cost and time to issue resolution</td>
<td>2) X</td>
<td>2) Estimated between 4X and 6X (Depending on Organisational Response time provided by - NMVO, Regulator and Manufacturers)</td>
</tr>
<tr>
<td>ADMINISTRATION:</td>
<td>Visibility and traceability of usage with proactive management of service levels Fingerprinting every scanning device identity with every transaction</td>
<td>No centralised visibility of the scanning devices using the service</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No fingerprinting of all devices using the service</td>
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<tr>
<td>RESPONSE: Response time measured in the execution of a medicine authentication from the pharmacist’s viewpoint (300ms)</td>
<td>Guaranteed with documented track record</td>
<td>Not yet demonstrated because of the additional interface</td>
</tr>
<tr>
<td>TRAINING: Ease of initial training and continuing professional development for the Pharmacist</td>
<td>Single Identical Message Graphical User Interface across all Pharmacies in a given country</td>
<td>Dependent on multiple software vendors</td>
</tr>
<tr>
<td>AVAILABILITY: Minimum down-time due to elimination of system faults (including externalities such as third party software upgrades)</td>
<td>Current measured availability: 99.998%</td>
<td>Non measurable: compounded by introducing multiple suppliers</td>
</tr>
<tr>
<td>THROUGHPUT: Capacity to deal with peak volumes of messages and large number of PMRs and Pharmacies with no degradation of performance</td>
<td>Current throughput of 2.5 million scanned Medicines per day and tested for Scaling up to 20 times with virtually no degradation</td>
<td>Still in a pilot phase with no significant volumes</td>
</tr>
<tr>
<td>MEETING FMD REQUIREMENTS:</td>
<td>Yes</td>
<td>No</td>
</tr>
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