AdeptPackaging
PACKAGING ENGINEERS & CONSULTANTS

European Medicines Verification System

Onboarding and Master Data Challenges

An Adept Packaging White Paper

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By February 9, 2019, pharmaceutical brand owners and market authorization holders distributing products within the European Union and Switzerland will participate in the European Medicines Verification System (EMVS). The EMVS is an interoperable set of databases composed of a centralized regional hub (EU Hub) and several other national level systems, or National Medicines Verifications Systems (NMVS). This network of verification systems will form the backbone of the EU's pharmaceutical serial number verification system, benefiting supply chain partners such as distributors, wholesalers, and pharmacies, and most importantly, patients.

In a letter from August 6th, EMVO reminded pharmaceutical brand owners and market authorization holders of the urgency of a timely onboarding. As of that date, an estimated 2,000 Onboarding Partners (OBP's) still need to connect to the EMVS EU Hub. Only 841 OBPs have signed the required agreements, 453 have reached the Technical Onboarding phase, and only 106 of them are connected to the production environment of the EU Hub.[1]

Considering that 5 months remain before the Delegated Regulation comes into force, and a typical OBP onboarding process can take up to 6 months to be fully completed, many pharmaceutical brand owners and market authorization holders are at risk of not fully complying with the Falsified Medicines Directive.[2]

Adept Packaging is putting forth this white paper to shed light on this time sensitive problem and offer strategies for solving it.

I. Connecting to EMVS/NMVS Services

At the core of guaranteeing the interoperability of any multitiered database repository system lie the understanding of its operating business rules and the strict adherence to explicit master data models. With up to 32 possible national verification services, adherence to these standards becomes critical.

Pharmaceutical brand owners and market authorization holders need to assess and address several areas before initiating their onboarding process:

1. Define the structure of Onboarding Partner (OBP) that best suits the mix of affiliates, CMOs and parallel traders for each product.
2. Assess if OBP's master data use is consistent with the EMVO/NMVS requirements.
3. Decide on the use of a direct connection or a Gateway provider.

Each of these assessments and decision points need to take into consideration the intricacies of each product's supply chain and distribution model. Furthermore, country-specific distribution volumes and the possibilities of parallel trading need to be added to the equation as pharmaceutical brand owners and market authorization holders decide on their EMVO EU Hub onboarding strategy.

The above challenges are major hurdles and deal solely with "connecting". Distribution of data in an acceptable format must still be addressed.

Onboarding Partner (OBP) Model Definition

The critical first step for onboarding is determining which Onboarding Partner (OBP) model to use. According to the Delegated Regulation, pharmaceutical brand owners and market authorization holders with and without parallel distribution activities are required to upload unique identifiers and related information to the EMVS before their medicinal products are released for sale or distribution.[3] An On-boarding Partner (OBP) is a legal entity that is authorized to sign on behalf of pharmaceutical brand owners and market authorization holders.

Pharmaceutical brand owners and market authorization holders must be affiliated to the entity acting as the OBP among the corporation. The OBP company will only be allowed to upload product data for its affiliates and contract manufacturing organizations (CMOs) as long as the marketing authorization of the related product(s) lies within the OBP corporation.

Without the guidance and knowledge of implementers who understand these issues, an unavoidable negative impact on costs and time will occur.

Master Data Rules

A The appropriate use and adherence to common master data standards is critical to interoperability and seamless systems integration due to its commonplace in multi-tiered database systems. EMVO's ***EMVS Master Data Guide***[4] establishes clear criteria as to the minimum requirements for Master Data handling across OBPs, Gateway Providers and EMVS/NMVS systems.

Unfortunately, the multiplicity of technical details relating to master data use is compounded with each trading partner and the existence of multiple legacy data and product identification standards across the supply value chain. To complicate things further, these standards can also be interpreted and implemented in a variety of ways. Differences, large or small, are likely to result in costly exceptions and errors. Mapping to EMVS Master Data requirements while retaining functionality of legacy IT systems becomes a critical element of a successful OBP onboarding.

Subject matter experts on master data management, mapping, and deployment become a critical resource for the successful onboarding of OBPs. Failure to access such human capital will irreversibly slow down your progression onboarding as an OBP.

Direct Connectivity or Use of a Gateway Provider

OBPs connecting to the EU Hub will have access to three different environments. Progressive development and testing through these are necessary to ensure that connections to the Production Environment (PRD) are validated and stable.

- ✓ **Integrated Test Environment (ITE):** ITE will be accessed as a sandbox by the OBPs to perform the first development of the connection and do a first integration test.
- ✓ **Integrated Quality Environment (IQE):** When the OBP is confident the developed interface is ready for testing, the IQE will be used to perform the Quality & Certification test.
- ✓ **Production Environment (PRD):** After the OBP passes the Quality & Certification testing, access will be granted for the Production Environment. Only validated systems can send data into the EU Hub.

Conversely, the appropriate selection of a third-party Gateway provider is also critical. Approval by the EMVO to act as gateways does not mean a pharmaceutical brand owner or market authorization holder is buying a commodity product. All vendors are not the same, and not all will seamlessly integrate to the legacy serialization system infrastructure and business processes.

Effectively sifting through the sales and marketing cruft to select the most beneficial vendor can be challenging. Additionally, product distribution, volumes, and supply chains may differ greatly from those competitors in the same markets and spaces. Careful assessments must be performed to ensure these selected Gateway Provider can safely manage the unique use cases posed by specific pharmaceutical supply chains.

Regardless of the connectivity type, the development, project management, and successful testing required for the onboarding process can be time-consuming and complex. Access to experienced project managers and engineering personnel will minimize risk and expedite the execution of these time-sensitive compliance activities.

Conclusion

Adept Packaging can help navigate through the process of establishing the best strategy for onboarding into the EMVO's EU Hub and navigating the complexities surrounding master data requirements, connection architecture, selection of Gateway Providers, and managing the complex NMVO fee structures as these last entities are launched. Adept Packaging will ensure each unique solution reflects the lowest cost of ownership for the best possible value.

Adept Packaging and its staff of subject matter experts and engineers have been in the Track, Trace, and Serialization space since inception. Our methodologies for implementing and solving sophisticated, as well as simple, serialization problems have been consistently tested and proven effective. Contact Adept Packaging for a consultation today.

www.adeptpackaging.com

Sources

Reference 1: LETTER OF ANNOUNCEMENT - EMVO notice of the On-boarding on time, dated Aug 6, 2018

Reference 2: Falsified Medicines Directive 2011/62/EU

Reference 3: Delegated Regulation 2016/161

Reference 4: EMVS Master Data Guide (EMVO_0122, V2.0)