PSQR SOFTWARE

How a distributed solution can assist with MDR Track and Trace compliance

Interconnecting actors and ensuring data flow across medical device supply chains

The EU Medical Device Regulation (MDR) would have fully applied from the 26th of May 2020. Due to the tragic COVID epidemic, the EU Commission and Parliament agreed to postpone this date by one year, until 26 May 2021. However, this postponement will only enter into full force after the member states have approved the proposal and it has been published in the Official Journal at the end of May.

Track and Trace within the Medical Device Regulations

The EU Medical Device Regulation (MDR) is a progressive regulation aiming to improve patient safety by governing the production and distribution of medical devices in Europe.

MDR is replacing the Medical Device Directives (MDD) and although some Medical Device Manufacturers have already adopted the regulations there are many who are still making changes. Some of these adjustments include serialization and ID issuing relating to products and packaging, incorporating standardized product classifications, obtaining conformity certificates for their products through Notified Bodies and much more.

Another important aspect of MDR is the requirement to identify and track and trace medical devices within the supply chain.

Article 25 (of MDR) states that "distributors and importers shall cooperate with manufacturers or authorized representatives to achieve an appropriate level of traceability of devices."

With Article 25 in mind and the strict requirements around serialization and post market surveillance and vigilance, it is evident that a Track and Trace functionality (and capability) will be an effective tool for medical device companies and economic operators to become (and to remain) MDR compliant.

Heterogeneous and disparate supply chain

A number of industries have regulated track and trace requirements, some with very strict rules. The track and trace rules for MDR are more lenient though, as the medical device industry has unique challenges.

Recent research revealed that the European medical device industry consists of 20 000+ companies. Furthermore the economic operators forming the network(s) of supply chains include hundreds of manufacturers, importers, distributors, resellers and medical service providers such as hospitals, clinics, and medical practitioners.

Due to MDR, each of these economic operators along the supply chain, must not only keep track of all devices they receive and supply to a next actor in the chain, they must also conduct a series of validations to ensure they are not passing on illicit/non-compliant products. Additionally, they need to be able to track and report on these activities.

Another reality is that the actors across the network(s) of supply chains vary in size - from small entrepreneurial companies to big international conglomerates.

Each of these actors have to play a role in the ecosystem and each player must comply on equal terms with the regulation. However, there are vast differences in their infrastructure, IT systems, logistics and track and trace capabilities.

So how can the medical device industry achieve compliance with Article 25 of MDR?

Is a centralized IT system or solution the answer?

Some would say that the European Data-bank on Medical Devices (EUDAMED), the current central European repository used in collecting information about medical devices, can be an answer - but track and trace is not in the current or future scope of EUDAMED.

Presently EUDAMED is a secure, web-based portal that acts as a central hive (repository) for the exchange of information between National Competent Authorities (NCAs) and the European Commission. Although EUDAMED will be open to the public in future the focus of the repository is to improve transparency and coordination of information regarding medical devices available on the EU market.

The track and trace requirements, as well as the reporting of the journey of medical devices and post market activity, vest with the manufacturers and economic operators within the network(s) of supply chains. To comply with these requirements another repository or centralized solution is needed. A solution outside of EUDAMED.

A centralized solution raises a number of practical questions though:

- **Who would own and manage a centralized repository solution for tracking and tracing of medical devices? (The landscape is too vast.)**
- **Who is going to operate (and pay for) such a centralized solution? (When there are so many actors involved.)**
- **If the solution was based on block chain - who is going to define the protocol, and pay for the overhead?**
- **How can data flow between actors, and across the chain, and still be secure... and without competitors having access to it?•**
- **Who is going to define the standards and the requirements of the system, and enforce compliance?**
- **How will it all work when the serialization requirements for Class I, IIa/b, and III are different?**

Due to the complexity of the industry, and the varied needs from players across the supply chain, we are of the view that a centralized solution is not the most practical or ideal answer to MDR track and trace compliance.

What about a distributed interconnected approach?

Due to the disparities in business focus, obligations and sizes of the economic players - across the network(s) of supply chains - we believe that not all actors will want or need the same solution for MDR track and trace compliance.

Yet, their systems and solutions still need to interconnect for a number of reasons, which include but are not limited to:

- **Instances where a full medical device distribution report needs to be generated in 72 hours.**
- **When medical devices are to be recalled.**
- **In the event that queries are lodged at EUDAMED or at a Notified Body, and evidence needs to be supplied.**
- **Information and data of medical device journeys are required by the manufacturer.**

Apart from the full supply chain, interconnectedness is required on an individual level as well.

This is due to the fact that all economic operators need to keep (and be able to share) a record of information regarding medical devices received and supplied.

A distributed or MESH solution where actors can scope and create contact points and rules to collect and share information regarding the medical devices received and supplied will therefore benefit both the manufacturer and the individual economic operators along the networks of supply chains.

Within a distributed solution each operator will not have to interact with everyone in their network, but only with direct peers in the supply chain they are part of.

By transferring and sharing data via the distributed solution to direct peers, a digital twin of each medical device will be created within the MESH. This digital twin will - like its physical counterpart - only be shared up and down the supply chain.

We believe that a distributed or MESH solution will ensure that each operator, no matter their size, role or system, can assist in achieving an appropriate level of traceability of devices. It will also enable manufacturers to track the devices they have produced along the vast network(s) of supply chains

Linking up and building a MESH of solid track and trace technology can deliver such a distributed inter-connected approach. This can include one solution for each actor - or in some cases groups of actors sharing a multi-tenant repository solution to reduce cost of ownership.

A distributed or MESH solution where actors can scope and create contact points and rules to collect and share information regarding the medical devices received and supplied will benefit both the manufacturer and the individual economic operators along the networks of supply chains.

A solid track and trace repository

PSQR works with partners who deliver track and trace solutions for customers across the globe. Our white label technology, Saga, is used as the foundation of these solutions.

Saga is a solid EPCIS based repository that enables storing, processing and the analysis of billions of track and trace events in real-time.

Due to its scalability and adaptability our partners have successfully integrated Saga to deliver industry-, organization -, government - and/or regulation specific track and trace solutions.

Solutions based on Saga can be natively linked together to form a distributed interconnected solution for the medical device industry.

How will Saga Mesh work?

The Saga Mesh technology is based on the well known EPCIS standard from GS1. But rather than relying on predefined subscription links and queries, Saga Mesh proactively sends relevant messages to peers based on the track and trace data recorded.

The Saga Mesh platform therefore allows for data exchange in the most common technical formats and incorporate switching mechanisms, providing data compatibility across supply chains.

When a manufacturer produces, serializes, and packages medical devices they create and record EPCIS events to describe each action. When the medical device is ready for distribution, a shipping message is recorded and the system “looks up” the receiver(s) to find the destination system(s) - next direct peer or group of peers - to which the relevant information will be forwarded.

Should a peer not be part of the MESH, the solution will notify operators that the required data can be zipped and sent in another format like email, a file upload, or other. In this way, the MESH solution or repository performs graceful degradation as needed.

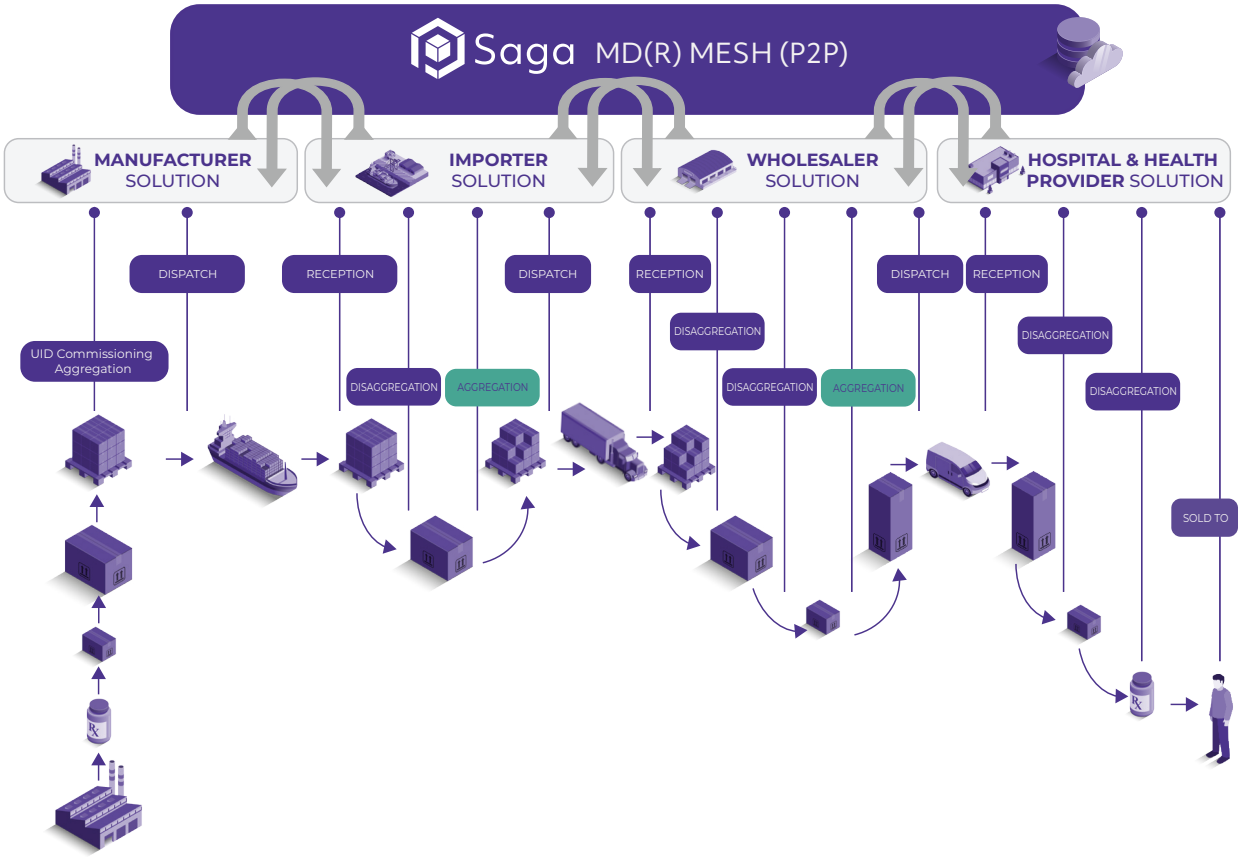
When data is received from an up-stream peer, the actor’s own solution may start running validation checks, business rules, and initiate other processes. This can happen even before the physical products have arrived at its destination, adding the feature to detect errors, omissions, or issues early.

Systems from the importer, distributor, or wholesaler will equally track disaggregations, aggregations of mixed shipments, and other events.

When ready or when the next action is flagged, they will send the data relevant for the given shipment or event.

The Saga Mesh repository hereby enables a distributed approach where the interconnectedness and the ability to share information can originate from anywhere in the supply chain, no matter the size of the business, its role or its IT system.

Flow of data in a typical medical device supply chain



And so can Saga Mesh assist with MDR Track and Trace compliance

The Saga Mesh repository empowers the manufacturer and unique economic operators to cooperate with each other to achieve an appropriate level of traceability of medical devices.

It gives the actors across the network(s) of supply chains the ability to collect and share information - about the medical devices they receive or supply - with direct peers.

By interconnecting actors within the network(s) of supply chains, Saga Mesh can assist the medical device industry with MDR Track and Trace compliance.

We believe that over time the data ecosystem within the medical device industry will converge to a few solid standards for data exchange. This will comprise of natively compatible solutions like Saga Mesh (EPCIS) and a number of data exchange mechanisms to convert messages to or from formats preferred by the actors within the applicable supply chains. All together forming a Distributed Track and Trace Data Network or Mesh.

PSQR

PSQR - We are Track and Trace Software Experts

PSQR is a Danish software development company that specializes in highly scalable software for storing, processing and analysing vast amounts of supply chain data. The company partners with track and trace software integrators, solutions providers, consultancies and industry bodies to bring best of breed IT Solutions to the world of Traceability. Hereby empowering manufacturers, corporations and governments across the globe with digital track and trace capabilities and the ability to tell the true story of the origin, journey, whereabouts, and consumption of products and resources across the supply chain.

Reach us at www.psqr.eu and on LinkedIn or send us an email at info@psqr.eu

Authors

EMANUEL GREISEN
Managing Director
egr@psqr.eu

JUANITA VAN DER WATT
Head of Marketing and Communications
jvdw@psqr.eu

PSQR

Frederiksborggade 15 | 6-7th floor | DK-1360 | Copenhagen | Denmark