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UDI-DATA ENTRY IN EUDAMED LESSONS LEARNED

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BIG CHALLENGES

The MDR and IVDR bring with them a multitude of new requirements – and UDI management in EUDAMED is no exception. Especially when a certain amount of UDI data is reached and data complexity increases, it quickly becomes clear that more is needed than just access to one's own data. Structure, processes, and practical knowledge are crucial.

OVERVIEW

- When manual entry into EUDAMED works.
- How to prepare yourself optimally.
- What unexpected pitfalls you may encounter.
- Which strategy will prepare you for the future.
- What is most likely the greatest threat to your market authorisation.

LESSONS LEARNED

Complete Data Saves Nerves and Time

Assumption
'I've basically got all the data together. I'll add the rest when I upload it.'

Incomplete data sets regularly result in error messages when uploaded to EUDAMED.

Although these can be corrected, the effort involved is considerable. Experience shows that those who make corrections during the upload process need at least twice as long. This is because instead of simply transferring the data, it has to be revised several times. This also unnecessarily prolongs the 'data collection' step. Error detection can be particularly tedious and time-consuming in the case of XML bulk uploads.

Check your data in advance to ensure it is complete – both in terms of form and content. And don't forget the EUDAMED business rules!

LESSONS LEARNED

Manual Upload Is Rarely the Best Choice

Assumption:
'I only have 300 UDIs. I'll just enter them manually quickly.'

Yes, manual uploading via the EUDAMED portal is possible in principle.

However, once you reach a certain number – especially with more complex datasets – it is worth considering automated alternatives. EUDAMED itself recommends using external software solutions for M2M when you have a large number of UDIs.

In addition to the number, consider the complexity of your data. This is because manual uploading is not only time-consuming but also prone to errors. It is easy to lose track of which UDIs have already been transferred. Versioning is often not carried out at all or only in confusing Excel files – without validation or traceability.

Plan with a system for secure and traceable data transfer!

LESSONS LEARNED

The Eudamed Nomenclature Is Not an Immediate Success

Assumption:
'I already know what EUDAMED means by the fields.'

Many fields in EUDAMED appear self-explanatory at first glance. However, there are dependencies and special features that are not always obvious – for example, in the 'Medicinal Product' field. Some information cannot be changed after the initial upload. In the worst case, a new UDI must be applied for.

Work with the official EUDAMED wording right away – this will save you a lot of effort later on.

*Definition according to EUDAMED UDI Data Dictionary: 'Defines if the Device contains substances which may be considered medicinal products' (FLD-UDID-158) is used in XML files with the term 'medicinalProductCheck'.
This refers to the presence of a substance which, on its own, is considered a medicinal product, such as a drug. This is often misinterpreted due to the choice of terms used by EUDAMED and has far-reaching consequences for the registration of the Basic UDI-DI and UDI-DI. Once entered in EUDAMED, this information cannot be subsequently changed or deleted. A new UDI must then be assigned.

LESSONS LEARNED

UDI Management Is Not a One-off Project

Assumption:
'I only have to do this once.'

With the first upload, you comply with MDR requirements – but that's just the beginning. Without regular maintenance, the next update will quickly become another major project. In addition, other countries are preparing their own UDI requirements (e.g. Australia, Switzerland). Audits are also increasingly asking how you keep your data up to date.

Establish a sustainable and auditable process for your UDI data management!

LESSONS LEARNED

Eudamed Is an External Factor – And It Needs to Be Taken Into Account

Assumption:
'I'll wait a bit before uploading.'

The final deadline for entering your data into EUDAMED may still be six to twelve months away. However, external resources such as consultants, software providers, and even EUDAMED itself are not unlimited and completely flexible in terms of time.

Allow sufficient lead time – including a buffer for:

- **establishing internal processes,**
- **compiling and validating data,**
- **the actual upload,**
- **and unforeseen delays.**

WELL PREPARED IS HALF REGISTERED

EUDAMED registration is not an immediate success – if you want to avoid pitfalls, you need to set the right course early on. Careful preliminary checks of data for completeness and accuracy are essential, as is strict compliance with EUDAMED business rules. If you don't work correctly here, you risk not only rejections but also unnecessary delays.

A well-designed data transfer system – ideally automated and with clear responsibilities – creates security and saves time. The closer the data is already structured in EUDAMED wording, the smoother the upload will be. At the same time, the handling of UDI data should be designed to be auditable and revision-proof in the long term – not only for EUDAMED, but also for internal and external audits.

And last but not least: plan with a buffer. Waiting times at EUDAMED or service providers due to fully booked capacities, regulatory changes or personnel bottlenecks in your own company can quickly throw your schedule off course. If you take these aspects into account at an early stage, you will remain capable of acting – and get your products into the European database safely and efficiently.

DO YOU NEED A SOFTWARE?

Not necessarily, but it simplifies the entire UDI management process. The first step towards making a decision is simple: enter a UDI into the database on a trial basis. If you then decide you would like to use the software solution, you can arrange a demo appointment with us or test the software in the free version.

ABOUT TRACEKEY

The better way to stay compliant.

tracekey solutions develops cloud-based SaaS solutions for the healthcare industry.

We help companies efficiently meet regulatory requirements and digitise complex processes. Building on our expertise in pharmaceutical serialisation, we have expanded our portfolio to include solutions for the medtech industry, including tools for UDI management and EUDAMED compliance. Our goal: secure, scalable and user-friendly platforms with fair pricing that meet the challenges of a dynamic market.

TRACEKEY SOLUTIONS GMBH

Alte Bahnhofstraße 20, 44892 Bochum, GERMANY

+49 234 545003-0 | info@tracekey.com | www.tracekey.com