Introduction

Poly Implant Prothese withdrawn from market: fraudulently manufactured gel

MDR officially published and enters into force

Devices certified under the MDD can no longer be sold or distributed

2010 2012 2017 2020 2025

EU Commission publishes proposal MDR, seeking to strengthen existing MDD

3-year transition period

MDR application

With only two years left what legislation changes need to be addressed first?

Objective

- Analyse impact of MDR on Johnson & Johnson Medical Netherlands sales & marketing
- Analyse impact of MDR on Johnson & Johnson Medical’s customers
- Identify how to add value to the business
- Identify how to help customers with transition to MDR

Theoretical framework

ISO 19600: compliance risk assessment model

The organisation should identify the likelihood of noncompliance and the severity of noncompliance.

Identification of compliance obligations

Risk analysis

Risk evaluation

Methodology

Purposeful sampling

In-depth stakeholder interviews n=21

Open coding with Atlas.ti 8

Analysis and recommendations

Results

Identification of direct and indirect legislation changes

Direct MDR obligations

- Implant card
- UDI system
- EudaMed Database
- Post-market surveillance

Indirect MDR obligations

- Reprocessing SUD’s
- Pre-market scrutiny

Legislation changes of impact per party

Johnson & Johnson Medical EudaMed Database Reprocessing SUD’s Post-market surveillance Implant card

Both Post-market surveillance Pre-market scrutiny

Customers

- UDI: Unique Device Identification
- SUD: Single Use Device

Discussion

A high impact legislation change is related with:

Mindset change: changing employees attitude is proven to be one of the hardest organizational changes, simultaneously creating the best opportunity to add value to the business.

Lack of knowledge: relevant knowledge on MDR is essential for appropriate operation for both Johnson & Johnson and their customers.

Patient safety: patient protection has the highest priority for both Johnson & Johnson Medical and their customers.

Conclusion

The highest impact of the MDR will be the PMS system and the new pre-market scrutiny. Therefore Johnson & Johnson Medical Netherlands should address these legislation changes first, to remain top position as well as help customers.

Key references

2. ISO 19600:2014 Compliance management systems - Guidelines