EU Medical Device Regulation (MDR)

Present and Future

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About...

Dr. Bernhard Weber

• Food Chemist
• Head of Laboratory, GLP Study director – ECON AG (13 years)
• Senior Consultant, Auditor, Quality Management Officer – HÄLSA Pharma GmbH, a Diapharm Medical device company (8 years)
• Associate Director Quality Management – Diapharm GmbH & Co. KG (since 2 years)

Consultancy Regulatory Affairs and Quality Management for Health Care Products (Medical devices, Food, Cosmetic)
We offer a holistic approach to supporting our clients

Providing Consultancy
- Strategic corporate & portfolio development
- Regulatory strategy
- Clinical and medical assessment
- Quality management strategy

Taking on Responsibility
- Legal Manufacturer Medical Devices
- Batch Release for Medicinal products
- Legal roles and representation

Performing Services
- Lifecycle management
- Regulatory Affairs
- PV/Medical
- GxP / QM
Medical Devices in the European market

- Medical devices: 297 (class I–III)
- CMO: 40
- Distributors: 30

Currently 32,000,000 packages in the market

Status November 2018
Outline

The Present
- Current surveys: Manufacturers & Notified Bodies
- Current strategies

The Future
- Opportunities
- Threats

Out of Europe
- Authorised Representative
The Present

Title of the report:
Die Patientenversorgung mit innovativen Medizinprodukten wird schwieriger
“Patient care with innovative medical devices becomes more difficult”

The title of the report is almost the final conclusion of the survey.
MDR is a comprehensive and very complex renewal of the legal situation for medical devices in Europe. Medical device companies have different strategies to meet the challenges –
But all companies struggle with ambiguities of MDR...
The Present – Problems of MDR

Companies in % evaluating the topic as „big“ or „very big“ problem
(number of companies = 282)
The Present

Uncertain legal situation (> 75%)

- Uncertain legal situation is the most important problem with MDR
- It is a "basic problem" as it impedes almost all companies to define strategies and operative plans
- EU Commission and MDCG are working on clarification of open questions - but are far behind their time plans
Unclear legal situation: An Example

**Article 85** Post-market surveillance report

Manufacturers of class I devices shall prepare a post-market surveillance report [...]. The report shall be updated when necessary [...].

**No time range / time point is defined when the initial report shall be issued.**

And what means: updated when necessary?

**Article 91** Implementing acts

The Commission may, by means of implementing acts, and after consultation of the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 85 [...] as regards the following:

- (b) [...] the provision of post-market surveillance reports, referred to in Articles 85, [...]

The Present
The Present

Personnel resources in regulatory affairs (> 70 %)
- New detailed requirements for Technical Documentation
- Enhanced verification of scientific studies (plan, method, report)
- Increased General Safety and Performance Requirements

New Requirement!

Person(s) Responsible for Regulatory Compliance (Article 15)
Responsible for:
- Conformity of produced medical devices
- Technical Documentation
- Post-market surveillance
- Vigilance
The Present

Short transition periods (65 %)
• No additional period for class I
• No significant changes to legacy products until 2024

Capacities at the Notified Bodies (60 %)
• (see following slide)

Certification costs (60 %)
The Present

Team-NB members capacities

Team-NB-Press-Release-Survey-Capacities-February-20190228
The Present - and the Future?

Expected Consequences

**Difficulties in bringing innovative products into the market (79%)**
Less innovations until legal situation will be clarified, personnel resources will be available and capacities of Notified Bodies will be build up.

**Increasing costs during the access to the market (74%)**
- Technical Documentation (New or Update)
- Scientific Body of Data: Clinical evaluation, clinical studies, biocompatibility, usability

**Threat to the existence (35%)**
The Present

Current Strategies (1)

• Perform Gap analysis of existing product portfolio
• Clean product portfolio (investment vs. future market)
  Due to unclear legal situation quite often a pessimistic approach is used
• New developments are only initiated in order to save the brand
• Or: new developments are launched outside Europe
• If possible: change product category (e.g. cosmetic)
• Companies expand their distribution areas (global approach)
• Or: companies leave the medical device sector
The Present

Current Strategies (2)

*Surprise!*

- New companies enter the medical device market with innovative product ideas.
- Requirements of MDR are considered as protection for these new products (it is not so easy for a competitor to copy the product)
- New clinical studies are used to differentiate the own product to competitors

- Distributors, suppliers and service providers are implementing ISO 13485
- ISO 13485 is not required, but is considered as a competitive advantage!
The Future

Opportunities

• New products will offer new perspectives in wound care management (Enhanced clinical requirements will lead to better clinical evidence and better USPs for companies)
• Strengthened supply chain will reduce damaged or less effective products
• Strengthened requirements for usability will lead to more effective use, especially for lay persons
• Competitive advantage for large-sized companies with capacities to realize the “early bird”
• Combination of medical devices and non-medical devices are now regulated (accessories, procedure pack, system, parts and components)
• EU-Regulation instead of EU-Directive will lead to more harmonized acceptance of medical devices
• Harmonized EU market will become more attractive for companies outside EU
The Future

Threats

• For a certain time period less innovations can be expected due to the uncertain legal situation
• Investments in product updates, implementing of new processes and new developments will lead to higher prices and subsequent difficulties with reimbursement
• Competitive disadvantage for medium-sized and small companies
• Especially innovative start-up companies may need some kind of government funding
• Unclear legal situation may lead to legal disputes and court cases between companies, notified bodies and competent authorities – or even competitors.
Outside EU – Authorised Representative

The Authorized Representative (EU representative, EC-Rep) is already known under MDD 93/42/EWG

**Responsibility and liability will be changed with MDR**

MDR, Recital 35:

For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union.

Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative **legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations. […]**

Considering the role of authorised representatives, the minimum requirements they should meet should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's **person responsible for regulatory compliance.**
Outside EU – Authorized Representative Obligations of the Manufacturer (Article 10)

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<thead>
<tr>
<th></th>
<th>Responsibility to meet regulatory requirements</th>
<th>cannot be delegated</th>
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<tbody>
<tr>
<td>2.</td>
<td>Risk management system</td>
<td>cannot be delegated</td>
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<td>3.</td>
<td>Clinical evaluation</td>
<td>cannot be delegated</td>
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<td>4.</td>
<td>Technical documentation</td>
<td>cannot be delegated</td>
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<td>5.</td>
<td><strong>Documentation custom-made devices</strong></td>
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<td>6.</td>
<td>Declaration of conformity</td>
<td>cannot be delegated</td>
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<td>7.</td>
<td>UDI system</td>
<td>cannot be delegated</td>
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<td>8.</td>
<td><strong>Keeping technical documentation and making available for competent authorities / EU representative</strong></td>
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<td>Outside EU – Authorized Representative Obligations of the Manufacturer (Article 10)</td>
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<td>9.</td>
<td>Quality management system</td>
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<td>10.</td>
<td>Post-market surveillance system</td>
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<td>11.</td>
<td>Device information in EU languages</td>
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<td>12.</td>
<td>Corrective actions for non-conforming products</td>
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<td>13.</td>
<td>Recording and reporting incidents</td>
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<td>14.</td>
<td>Cooperation with competent authorities</td>
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<td>15.</td>
<td>Requirement to register external design and manufacturing organisations (Art. 30 (1))</td>
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<td>16.</td>
<td>Financial coverage for compensation of damages</td>
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Outside EU – Authorised Representative

Consequences

• Relationship between manufacturers, importers and authorised representative is clarified with MDR

• Due to changed responsibilities change to MDR will require new contracts between manufacturers and authorised representatives

• Due to increased liability of the authorised representative manufacturers have to expect more control measures of the authorised representative.