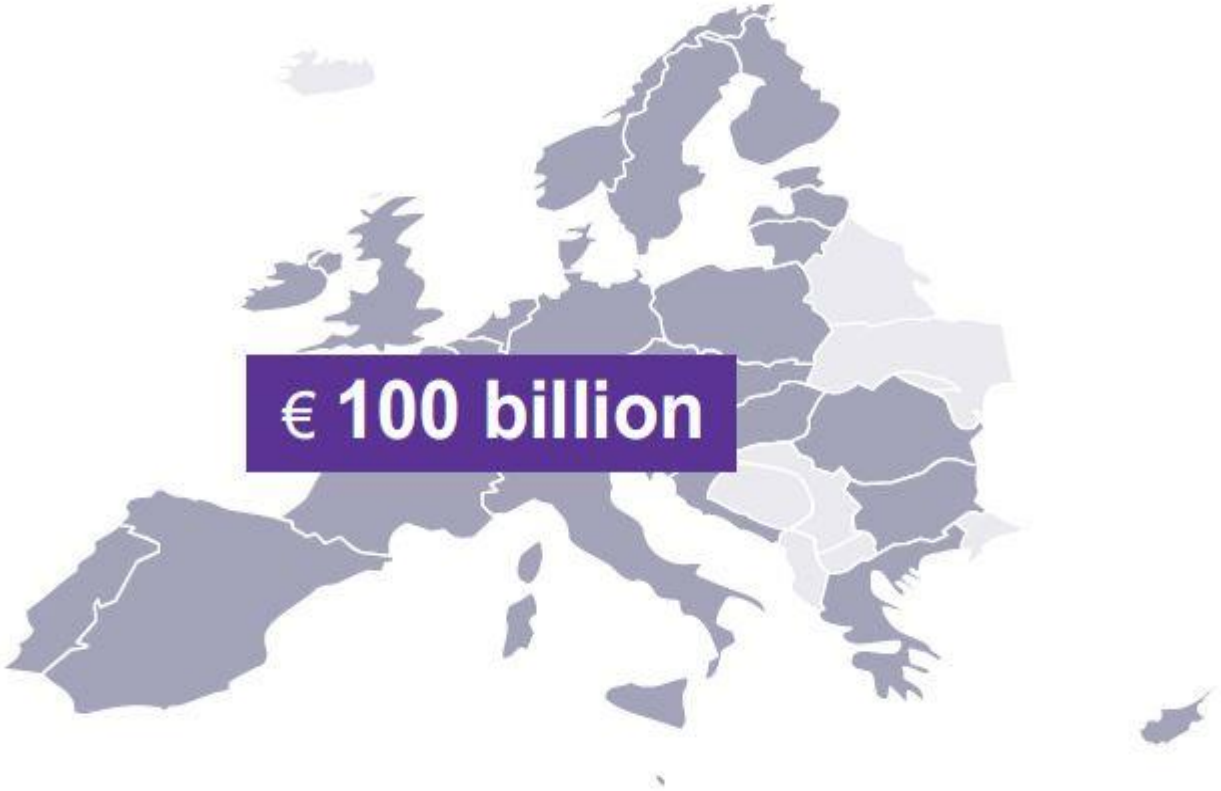
Webinar: Market Access and Regulatory Update for Medical Device Manufacturers
Series: Succeed in Germany's Healthcare Market 2015

Regulatory Update

Gabriel Flemming, Berlin, July 9th, 2015

GERMANY
TRADE & INVEST

The European Market(s): Mission Possible!



Source: EUCOMED

MEDDEV Revision

EUROPEAN COMMISSION

Regulatory framework

Current Legislation

Regulations relating to the safety and performance of medical devices in the EU were harmonised in the 1990s, following the New Approach legislative principles. The core legal framework consists of three directives:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)
- Council Directive 93/42/EEC on Medical Devices (MDD) (1993)
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)

They aim of these Directives is to ensure a high level of protection for human health and safety and a good functioning of the Single Market. These three main directives have been supplemented over time by several modifying and implementing directives, including the last technical revision brought about by Directive 2007/47/EC.

(http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/index_en.htm)

MEDDEV Revision

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European Parliament

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Council of the European Union

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Revisions of Medical Device Directives

Ongoing revision: Regulation proposals of the European Commission

In 2012, the Commission adopted a package of measures on innovation in health. The package consisted of a Communication and two regulation proposals to revise existing legislation on general medical devices and *in vitro* diagnostic medical devices.

MEDDEV Revision Timeline

Start in 2012:	2014:	06/2015:	Next 2015:	Next 2016:	2018 Conclusion:
European Commission Proposal	European Parliament First Reading	EU Council First Reading	Trilogue	Proposal adoption	Proposal adoption effective

European Commission

European Parliament

European Council
Council of the European Union

MEDDEV Revision Selected Issues

Notified bodies:	• Joint assessments by EU and national • Duty for unannounced audits including suppliers
(Re-)Classifications:	• some reclassifications I => IIa, IIb => III
Clinical evaluations and audits:	• Scrutiny for class III devices • Life cycle management • To be published in EUDAMED
Unique Device Identification System:	• UDI database with up to 21 elements per device

Reimbursement in Europe/Germany

1. Regulatory: Declaration of EU Conformity (CE)

↓

2. Reimbursement: Pass National Systems (Germany)

↓

In-Patient:
„Reimbursement unless on negative list“,
(Exclusion Right)

- Capital Goods(+3 yrs): Direct deal
- Other: DRG-System with lump sums
- Increase via „NUB“ negotiations and „ZE“

Reimbursement in Europe/Germany

1. Regulatory: Declaration of EU Conformity (CE)

2. Reimbursement: Pass National Systems (Germany)

Revision of „NUB" regulation:
- Coming up: direct involvement of Federal Joint Committee to evaluate new methods using high risk devices
- Expected to call for more clinical evidence
- Coverage with Evidence Development is already an established procedure (§ 137 e)

- I
- C
- Increase via „NUB" and „ZE" negotiations

<u>Out-Patient:</u>
„Reimbursement when on positive list",
(Approval Right)

- Practice Equipment: Doctor's purchase
- Practice Supplies: Regional clearance (KV)
- Medical Aids: National (GKV)

Contact

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