

# MARKET ACCESS AND REGULATORY UPDATE 2016

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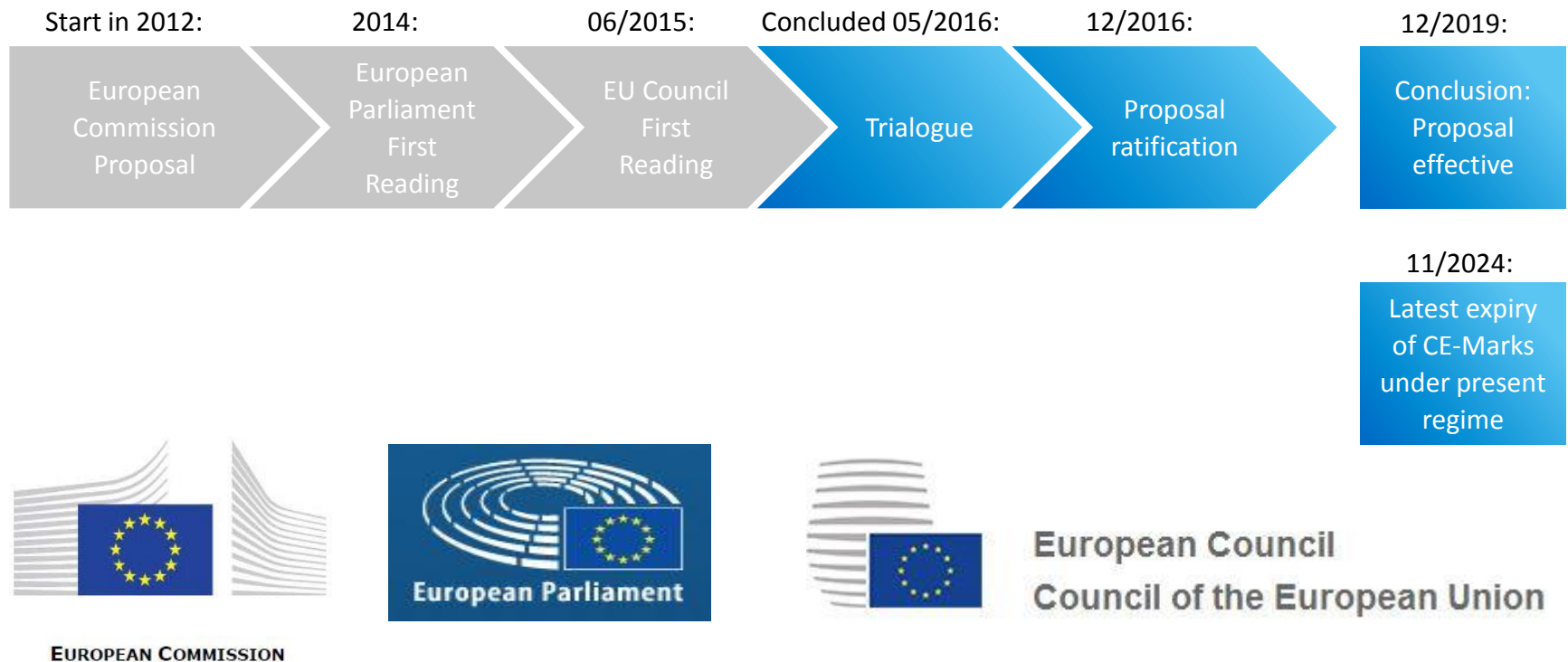
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# Market Access and Regulatory Update 2016:

## Revision of the European Medical Device Regulation 2016

### Revision Timeline and Involved Bodies



# Market Access and Regulatory Update 2016:

## Revision of the European Medical Device Regulation

### CE-Certification: Top Issues

- Some class I into class II, IIb into class III
- Unannounced (supplier) audits
- UDI database with 21 elements of information per device
- Individual clinical data necessary
- To be published in EUDAMED

### New Scrutiny Procedure

Notified Bodies to produce clinical evaluation assessment report **CEAR**



New EU **Expert Committee** may issue **scientific statement** based on **CEAR**



**Notified Bodies** to incorporate scientific statement, may provide certification with **restrictions**

# Market Access and Regulatory Update 2016:

## Clinical Partners for Regulatory and Reimbursement Issues

### German Medical Technology Clusters



### Cluster Services

- Connect companies, universities, other research organisations and hospitals
- Help obtain funding for joint R&D projects
- Political support
- Host industry events
- Training programs

# Market Access and Regulatory Update 2016:

## Market Access Check-Lists

### Regulatory Check-List

- Assign authorised representative
- Assign product safety contact
- Declare conformity with European Regulation and acquire CE-Mark
- For clinical trials apply at BfArM
- Notify DIMDI of marketing product

### Reimbursement Check-List

- Find clinical partners/key-opinion-leaders
- Obtain OPS and DRG-codes
- Apply for increased reimbursement via NUB route, install individual OPS/DRG
- Innovative products need clearance by G-BA

# Market Access and Regulatory Update 2016:

## Approach Buyers

### Buyer Options

- Hospitals
- Purchasing Groups
- Tenders
- Practices
- Care homes
- Homecare medical supply stores
- Pharmacies
- Out of pocket market

### Sales Channel Options

- Digital Sales
- „Distributors“:
  - License out to Manufacturers
  - Fee-For-Service Sales Teams
  - Agents/Sales Reps
  - Wholesalers
  - Consultants
- Direct Sales: Subsidiary

# Contact Us

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