Refurbishment ?
Re-use?
Single use ?

Rainer VOELKSEN
President Regulatory Affairs Professionals Society RAPS
c/o Swiss Federal Office of Public Health, Bern / Switzerland
AHC - AHWP, 19 November 2014, Seoul / Korea
Disclaimer

The following presentations reflect only the personal view of the author.

Thanks to some colleagues of whom I picked some slides (amended)!

Errors can only be attributed to myself.
Different legal status

- **Refurbishment**: complete “overhaul” of a used product by the manufacturer: replacement of all parts which could show wear and tear (batteries, used parts, ...). Declared as such by the manufacturer.
- No new “placing on the marker” – no regulation (but maintenance obligations)
- **Second hand**: direct sale from one hospital to the next – no regulation (but maintenance obligations)
- **Single use** is single use is single use: as defined by the manufacturer
- **Re-use**: example instrument sets: usually cleaned (and sterilized) by the user, sent back to the manufacturer, sterilized again and functioning to be verified. Sent out again for next OP.
- Regulations on re-use differ by Member State but strict cleaning and sterilization standards, some Member States do not allow external 3rd party sterilization subcontractor.
European Medical Devices Regulations?

Rainer VOELKSEN
President Regulatory Affairs Professionals Society RAPS
c/o Swiss Federal Office of Public Health, Bern / Switzerland
AHC - AHWP, 19 November 2014, Seoul / Korea
Topics

I. Europe before the Directives
II. Reason and background on the Directives
   a. Free movement of goods
   b. Common regulations across Europe
   c. Authorities focus on clinical trials and post-market
III. Review of the experience with the Directives
IV. Scenarios for next steps: Regulations vs strengthening the system
V. Conclusions
Europe: the idea of free trade of CE marked medical devices

• “Passport” to verify quality and safety
• Single market
• Nothing on reimbursement
• Based on quality management system
• Split into Competent Authorities (Government) for clinical trials and post-market and Notified Bodies (private but controlled by Government Designating Authorities) for the pre-market QM standard certification and where necessary product type certificate
Europe end of 1980ies / 1990

EU with 12 Member States
“New and Global Approach” developed
Early regulations (before 1990)

• Material tests (mostly joint implants) in some Member States
• Performance tests for batteries for pacemakers etc in some Member States
• General electrical safety requirements in some Member States
• Mechanical tests of prostheses in some Member States
• Each “approval”, verification, notification only valid in one Member State
• Only 12 EU Member States at that time
• Start of the New and Global Approach in the EU: one CE mark as sign of safety and quality means the free market access in all Member States
• No additional public service structure but out-sourcing to private bodies

- active implantable Medical Devices (AIMDD) 90/385/EEC
- «classical» Medical Devices (MDD) 93/42/EEC
- In-vitro Diagnostic Medical Devices (IVDD) 98/79/EC
Today: EU Directives & national implementations

Main Directives
- 90/385/EEC (AIMD)
- 93/42/EEC (MD)
- 98/79/EC (IVD)
- EU Reg Nr.765/2008 (Accr./Marketcontrol)
- EU Reg 920/2013 Control of NB

Amendments
- 2000/70/EC (Blood and plasma derivatives)
- 2003/12/EC (classification of breastimplants)
- ...

Member States etc transpose into different National Laws

DE:
- MPG
- MPV
- MPSV
- MPKPV
- ...

PT:
- ...
- ...

CH:
- HMG
- MepV
- HFG & VO’s
- ........
- MRA
- ...

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AHC-AHWP Seoul Korea
Experience

- Variable implementation and interpretation in the Member States
- Common classification lacking
- From 12 to 28 Member States: lack of mandatory collaboration
- EU paved the way for QMS recognition through GHTF (now IMDRF)
- Too many Notified Bodies, each assessed by one national Designating Authority creates large variety across the EU
- Criticism from industry, public, politics
- Formal review with public consultation
- New “proposed regulations” in September 2012 (switch from Directives will mean mandatory collaboration, one and the same text for all member States, stricter and harmonized controls of NB’s)
European political process

**European Commission:** Proposes Legislation TECHNICAL

**European Parliament:** Proposes Amendments POLITICAL

**Council = 28 Member States:** Proposes Amendments TECHNICAL/Political

Negotiate and agree on final text
Current Status of the Process

ROUND 1 (technical)

COMMISSION DRAFT text proposal (26 Sept 2012)

Amending draft Commission text

ROUND 2 (political)

Parliament ENVI Position (25/09/2013)

Amending draft Commission text

Parliament Plenary Position (22/Oct/2013) 1st reading April 2014

We are here

COUNCIL Position (= 28 Member States) (Dec 2014?)

ROUND 3 (political)

Negotiation between Parliament and Council (potentially as of Jan 2015 ?)

Agreement = Adoption of Final Text (Q1/2015 ?)

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The political timetable

Council reaches political agreement?

Greek Presidency

Italian Presidency

Latvian Presidency

Luxembourg Presidency

Dutch Presidency

Jan 2014

July 2014

Jan 2015

July 2015

Jan 2016

Parliament elections

Rapporteurs appointed

Begin trilogues?

New Commissioners in place

Conclude trilogues?

Entry into force?
The formal process

1. Proposal from Commission
2. First reading by EP position
3. Amended proposal from Commission
4. First reading by Council
5. Council approves all EP's amendments
6. Council can adopt act as amended (without further amendments and in the wording of EP's position)
7. EP has approved proposal without amendments
8. Council can adopt act without amendments and in the wording of EP's position
9. Council position at first reading
10. Communication from Commission on Council position at first reading

11. Second reading by EP
12. EP approves common position or makes no comments
13. Act is deemed to be adopted
14. EP rejects Council position at first reading
15. Act is deemed not to be adopted

16. EP proposes amendments to Council position at first reading
17. Commission opinion on EP's amendments
18. Second reading by Council
19. Council approves amended Council position at first reading
(i) by a qualified majority if the Commission has delivered positive opinion
(ii) unanimously if the Commission has delivered negative opinion
20. Act adopted as amended
21. Council does not approve the amendments to the Council position at first reading
22. Conciliation Committee is convened
23. Conciliation procedure
24. Conciliation Committee agrees on a joint text
25. EP and Council adopt act concerned in accordance with joint text
26. Act is adopted
27. EP and Council do not approve joint text
28. Act is not adopted
29. Conciliation Committee does not agree on joint text
30. Act is not adopted
Outlook

- Many combinations possible in Council

- With the large member states’ differences, coalitions of small member states can have impact
Proposal by the European Commission

EUROPEAN COMMISSION

COM(2012) 542 final
2012/0266 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

and Regulation (EC) No 1223/2009
Tomorrow: EU regulations

- Proposal IVD COM (2012)541 final
- Proposal on Medical Devices and... COM (2012)542 final
- Reg (EU) Nr.765/2008 (Accreditation/Market Surveillance)

**MS DE:**
- IVD EU Reg.
- MD EU Reg.
- Reg 765/2008

**MS PT:**
- IVD EU Reg.
- MD EU Reg.
- Reg 765/2008

**CH Rev.:**
- HMG oder MPG ?
- MepV’s
- HFG & VO’s
- ......
- MRA ?!
- ...
Structure overview summary of proposed regulation

10 Chapters
1  – Scope & definitions
2  – Making available of medical devices, MAID
3  – Identification & traceability
4  – Notified Bodies
5  – Classification, conformity assessment
6  – Clinical evaluation & investigation
7  – Vigilance and market surveillance
8  – Governance
9  – Confidentiality
10 – Final Provisions
Structure overview summary of proposed regulation

16 Annexes
I – General safety & performance req.
II – Technical Documentation
III – EU Declaration of Conformity
IV – CE marking
V – Device & Operator registration, UDI
VI – Requirements for NB
VII – Classification criteria & rules
VIII – Full quality assurance and design examination
IX – Type examination
X – Production Quality Assurance / Product Verification
XI – Custom made devices
XII – Content of certificates
XIII – Clinical evaluation / PMCF
XIV – Clinical investigations
XV – Products without medical claim covered
XVI – Correlation table Directives vs. Regulation
PMA Parliament:
“Assessment procedure in specific cases”
Scrutiny mechanism for certain conformity assessments

ACMD - Assessment Committee for Medical Devices
MDCG – Medical Device Coordination Group

MANUFACTURER SUBMITS FILE*

NOTIFIED BODY

COMMISSION

MEDICAL DEVICES CO-ORDINATION GROUP (MDCG)

ACMD clinical assessment ?

20 days

Yes / No Scrutiny

SCRUTINY PROCESS STARTS

MDCG SCRUTINY

30 days

INFO REQUEST

TIME

MDCG FINAL COMMENT

60 DAYS

ACMD clinical assessment: Review of documentation, may include samples and visits

If documentation is complete and no clock stop: 60 days

* Applies initially only to all new class III devices and can be expanded to other device classes and device categories.

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Proposed Conformity Assessment

Class I
- Annex II (Tech. Doc.)

Class I sm
- Annex II (Tech. Doc.)

Class IIa
- Annex II (Tech. Doc.)

Class IIb
- Annex II (Tech. Doc.)

Class III
- Annex II (Tech. Doc.)

Annex X
- Production QA
- Product verification

Annex VIII
- Full QA (no DE)
- Full QA (incl. DE)

Annex IX
- TE

Clinical Investigation – Article 50 to 60
Annex XIV – special rules for PMCFU

Custom Made Devices
Article 19, Annex XI

DoC Annex III

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“Nando” list of Notified Bodies

- 82 NB before 2010 for MD
- 75 NB (21 June 2014)
- 70 NB (11 Oct. 2014)

New EU implementing Regulation 920/2013

Proposed “Regulation”

Prognostic
Experience with the 2012 “immediate measures”

• EU Implementing Regulation 920/2013 from Sept. 2013, effective since January 2014: assessment of NB with multi-national audit team plus EU –Food and Veterinary Office (Inspectorate)
• Monthly tcons/F2F meetings between all Member States in regards to Vigilance
• Strong collaboration and information exchange between all Member States in the area of clinical trials
• Strong new committee of the Member States
• Each “approval”, verification, notification only valid in one Member State
• Publication in July 2014 of the “experience under the immediate measures” by the EU Commission
Process

#4 2nd reading in Parliament
Parliament examines Council's position and approves it, in which case the act is approved; or rejects it, in which case the act will not enter into force and the whole procedure is ended; or proposes amendments and returns the proposal to Council for a 2nd reading.

#5 2nd reading in Council
Council examines Parliament's 2nd reading position and either approves all of Parliament's amendments meaning the act is adopted, or does not approve all amendments, leading to the convening of the Conciliation Committee.
IVDs: the quantum leap

- IVDs neglected in political discussion, but immense changes in the works
  - IVDs for ‘indirect medical purpose’ ("life style tests") likely to be regulated
  - Genetic testing practice requirements
  - Radical changes in conformity assessment / market access
Proposed IVD Classification

IVD Classification

Rule 1
- Blood screening
  - High-risk diseases

Rule 2
- Blood of blood compatibility

Rule 3
- Infectious diseases
  - Cancer testing
  - Companion diagnostics
  - Genetic testing
  - Congenital screening

Rule 4
- Self-testing
  - High-risk patient tests

Rule 5
- Specific IVD reagents
  - Instruments
  - Specimen acceptance

Rule 6
- None of the other rules

Rule 7
- Controls no assigned value

D
C
C
C
A
B
B

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AHC-AHWP Seoul Korea
Quo vadis, Medical Devices Regulation?
OUTLOOK

• Final system should be safe, thought-through and implementable
• Equal implementation and interpretation throughout all Member States
• Less and more competent Notified Bodies
• Better classification for IVD
• More clinical trials required for more products
• Stronger and more effective collaboration between all Member States
• Stronger EU “Body” / “Committee” with mandatory decisions

• Safe products for all patients
Thank you – any questions?

Rainer.Voelksen@bag.admin.ch