National deviations in EU

Peter Löwendahl
March 2021

Hoff & Lowendahl

1

National Deviations

- Article 120(3)
- The overall EU landscape
- Managing differences
- Selected countries

Hoff & Lowendahl

2

Starting with …..

If you using the transition rule for MDD products….

Transitional requirements article 120 (3)

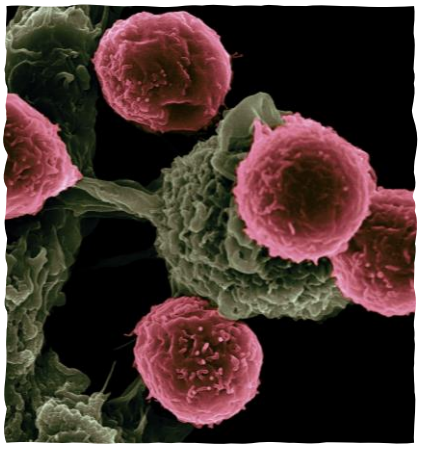
MDR requirements shall be followed for:

- post-market surveillance,
- vigilance reporting
- registration of products and economic operators

Article 120 (3) key issue to remember

- Provided there are no significant changes in the design and intended purpose.
- Needs to follow significant change guidance MDCG 2020-3
- Corrective action is not significant change

Clinical trials



- Not effected if started before May 25, 2021

but

- The reporting of serious adverse events and device deficiencies shall follow MDR

Overall EU landscape MDR

- You still need to investigate what the particular requirements are in each country
- Limited to the areas allowed according to MDR/IVDR

All EU countries have additional requirements above and beyond the language!

Additional national requirements

- Sweden
- Denmark
- Finland
- Germany
- France

SWEDEN

Chapter 7 in proposed Swedish law specifies

Föreslagna föreskrifter om:

- Specialanpassade produkter (2.3)
- Egentillverkade produkter (17)
- Blod och blodkomponenter i produktion
- Utbildningar som sakkunniga personer ska ha (15.1, 15.2 och 15.6)
- Det eller de språk som märkning och information ska vara skriven på (10.11) 2020:315
- Informationskrav i fråga om implantat (18)
- Kliniska prövningar (63.2c och 62.4j) Ute på remiss

Sweden Penalties in Chapter 5

§

Max ett års fängelse vid uppsåt eller av oaktsamhet

1) Enligt artikel 5 i MDR (Utsläppande på marknaden och ibruktagande)
2) Eller att språkkrav ej är uppfyllda

Till böter eller fängelse i högst två år döms den som med uppsåt eller av oaktsamhet påbörjar eller genomför en klinisk prövning

1) utan tillstånd,
2) utan att ha lämnat in en ansökan eller anmälan enligt artikel 70.1, 74, 75 eller 82.1 i förordning (EU) 2017/745

Sanktionsavgifter ska bestämmas till högst 100MSEK kronor.
Sanktionsavgifter för region, stat och kommun max 10MSEK

Hoff & Lowendahl

11

Other things….

- Rapporteringsskyldighet 87.1, 88.1 och artikel 89.8 enligt artikel 123.3 d)

Kapitel 4 Avgifter får tas ut för;

- Klinisk prövning,
- Klinisk prövning för utvärdering
- Anmält organ
- Artikel 59
- Reprocessare av engångsprodukter
- Exportintyg

12

Germany

MPDG (MPEUAnpG)

Hoff & Lowendahl

13

Germany – MPDG replacing MDG

Penalties:

- Max jail 3-5 years as before
- Non approved clinical trial and not registered product
- Misleading information on/about the product
- Max fines still 30 000 Euro also for persons

14

Germany. MPDG **MPEUAnpG**

- Section 74 of the MPDG obliges the authorities to act when an Economic Operator is inactive
- Safety officer now almost PRRC with personal responsibility
- Clinical trial requirements
- Language German, but for some proffessional devices English

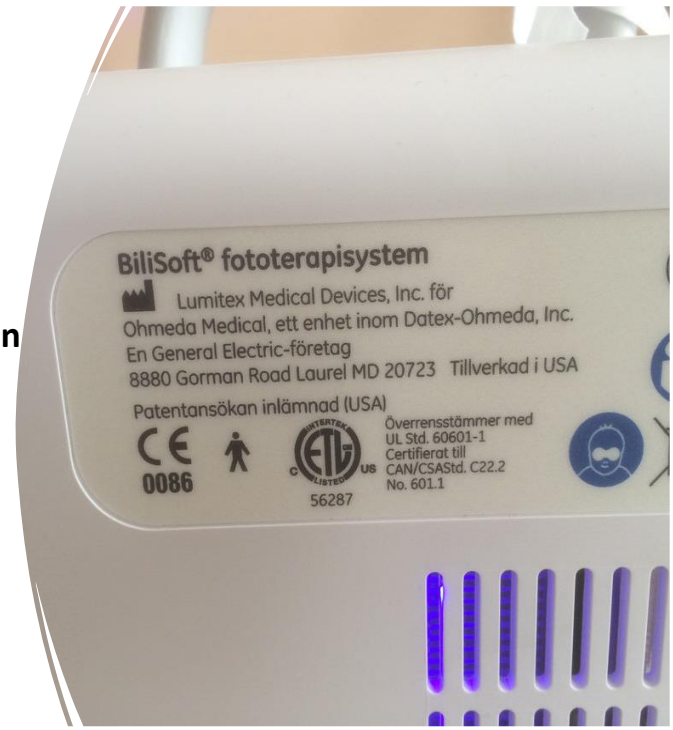
- Reprocessing allowed (but must be registered with authorities)
- Reporting and Registration requirements until Eudamed works

Hoff & Lowendahl

15

France ANSM

- **Requirement on agreement between manufacturer and distributor**
- **Not allowing reprocessing**
- **Clinical investigation**
- **Article 59**



16

Denmark

- Clinical investigations LOV nr 1853
- Language requirement
- Reporting requirements (Eudamed)
- Reprocessing
- Penalties
- Article 59

Finland

Modified law 24.6.2010/629 - 30.12.2019/1482

- Clinical investigations
- Language requirements
- Market surveillance
- Penalties
- Eudamed
- Article 59

Common areas

- Clinical trial – national requirements higher penalties
- Language requirements – some markets open up for english
- Transition rules for registration and reporting

Key take aways:

- Most countries add similar requirements but…
- Same same but different
- Watch out for significant changes if using MDD transition rule

Hoff & Lowendahl

www.lowendahl.eu
peter@lowendahl.eu
Phone Int + 46 (0) 722-313355