swissmedic

Online event

Information on the new medical devices regulation

Thursday, 2 September 2021

Clinical trials with medical devices

New requirements and changes to the legal requirements since 26 May 2021

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Harmonisation of Swiss medical devices legislation with the MDR

- Chapter VI of the MDR has resulted in amendments to the relevant laws, particularly TPA and HRA

- Comprehensive revision of the ordinances: MedDO, ClinO, and new ClinO-MD

- New ClinO-MD with provisions in the MDR for clinical trials with medical devices

- Revised ClinO still regulates
  - clinical trials with medicinal products (Art. 19 ClinO)
  - clinical trials with in vitro diagnostic medical devices and products according to Article 2a paragraph 2 TPA (Devit) (Art. 20 ClinO)

ClinO-MD: Trials with what products?

ClinO-MD	ClinO

• All products according to Art. 1. para. 1 MedDO
  • Medical devices and the associated accessories (excluding in vitro diagnostic medical devices)
  • Product groups without an intended medical purpose as per Annex 1 MedDO
• Products which incorporate, as an integral part, a medicinal product that only has a supportive function
• Animal devitalised products incl. devitalised derivatives
• Human devitalised derivatives
	• Medicinal products, incl. combinations according to Art. 2 para. 1 let. f + g MedDO
	• In vitro diagnostic medical devices
	• Products according to Art. 2a para. 2 TPA (human devitalised products excluding devitalised derivatives)
	• Transplant products
	• Gene therapies, GMOs
	• Transplantation
	• Other

MDR and clinical trials

- Patient safety, transparency, approval procedures
- Definition of "clinical investigation" taken from MDR (CH: "clinical trial")
  - Old Art. 3 para. l TPA: "Research project in which persons are prospectively assigned to a health-related intervention in order to investigate its effects on health or on the structure and function of the human body"
  - New Art. 2 para. a ClinO-MD: "Systematic investigation of a device involving one or more persons for the purpose of assessing the safety or performance of the device"

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MDR and clinical trials

Eudamed

- Introduction of the module delayed in the EU
- Transitional provisions for Switzerland (Art. 49 ClinO-MD)
  - Applications submitted as before via BASEC or medical devices information system (Swissmedic eMessage portal)
  - Registration of the trial according to Art. 64-67 ClinO, publication of results in international study registries
  - Coordinated assessment procedure according to Chapter 3 ClinO-MD not yet entered into force

Coordinated assessment procedure

- Sponsor can apply for a coordinated assessment of the trial via Eudamed
- Status: Voluntary if Eudamed is available, compulsory from 2027 for all member states

MDR and clinical trials: Approval procedure

Requirements from MDR for investigations according to Art. 62 MDR

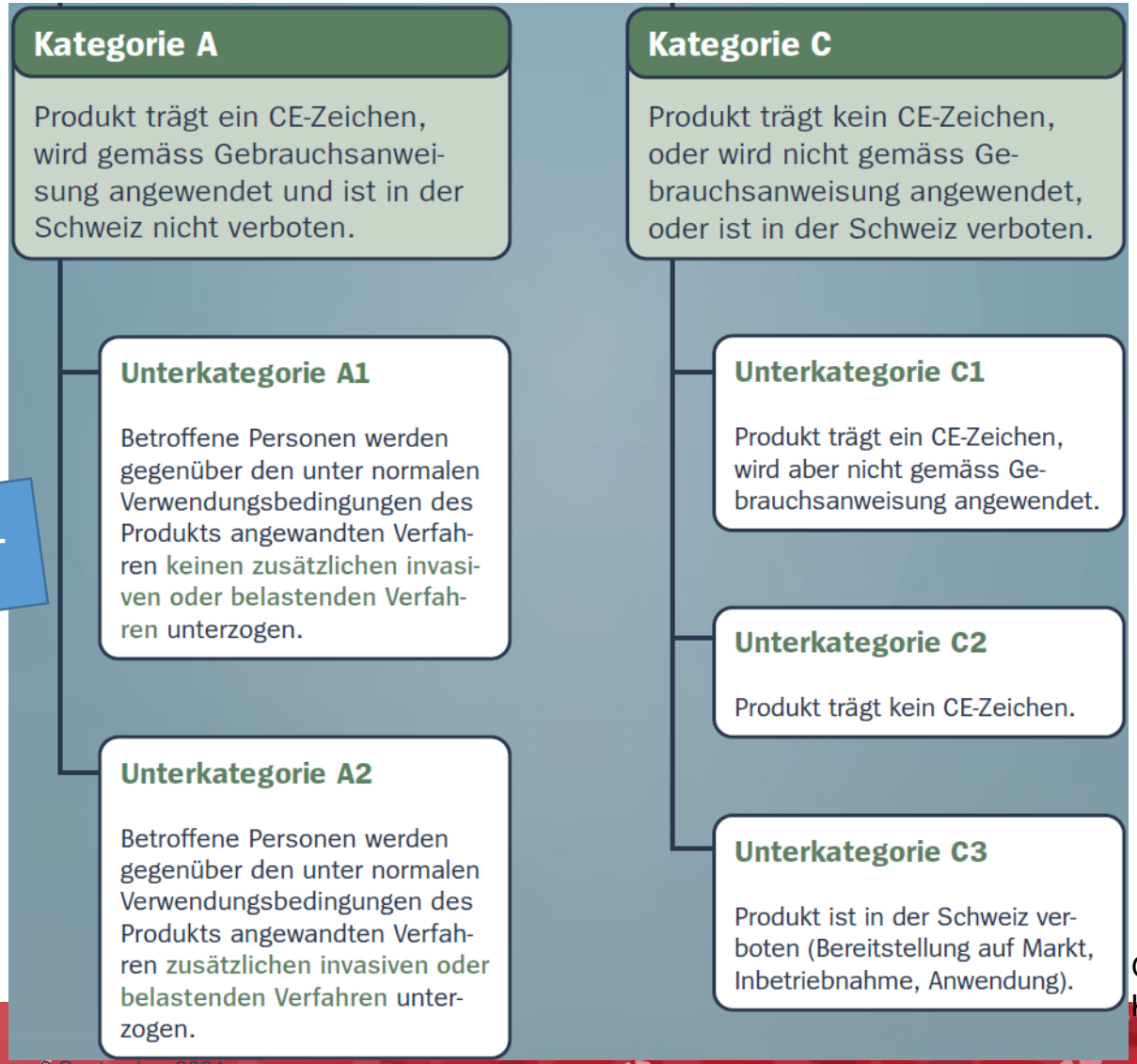
- 1 dossier with documents specified in Annex XV MDR
- Uniform deadlines for formal and content review
- 1 approval by member state
- No approval if negative decision issued by ethics committee

→ Implementation different in member states

Approval procedure: Categorisation of trials

Art. 6 ClinO-MD

Categorisation of clinical trials with medical devices



Kofam-Categorizer

Graphic: Kofam

Approval procedure: Parallel procedure in Switzerland

Art. 10-12, 16, 17, 19 ClinO-MD

Parallel review of Cat. C trials by Swissmedic and ethics committee

- Submission on the same day via BASEC and eMessage
- Application documents according to Annex 1 ClinO-MD
- EU-conforming deadlines for authorities and sponsor (Art. 12 and Art. 19 ClinO-MD)
- Legal hearing and option for supplementary submission unchanged
- Start of the trial after approval by Swissmedic possible

Swissmedic website and information sheet: www.swissmedic.ch/md-clinicaltrials-en

Approval procedure: Simplified review by Swissmedic

Art. 17 para. 2 and 3 ClinO-MD

- Verification of completeness of the application and fulfilment of the conditions specified in Art. 17 para. 2 ClinO-MD:
  - Cat. C1 or C2 trial with non-invasive device in class I or IIa
  - Use entails minimal risks at most
  - Written agreement between investigator and sponsor on adverse events
  - Sponsor operates a risk management system incl. safety monitoring

NEW

Swissmedic website and information sheet: www.swissmedic.ch/md-clinicaltrials-de

Substantial amendments

Art. 15, 20, 48 ClinO-MD

- Definition according to Art. 75 MDR
  - "Modifications that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation"
- Applies to Swissmedic and ethics committee
- Mandatory approval by ethics committee (Cat. A) or by Swissmedic and ethics committee (Cat. C), no ‘silent approval’
- Parallel approval procedure in Cat. C trials as for first applications

MDCG 2021-6 ‘Questions & Answers regarding clinical investigation’

swissethics guidance document on ‘Substantial modifications’: www.swissethics.ch

Safety reporting for Cat. C clinical trials

Art. 33-36, 38 ClinO-MD

- Guidance document MDCG 2020-10/1 and Table MDCG 2020-10/2 replace MEDDEV 2.7/3
- Reporting by the sponsor to Swissmedic and (lead) ethics committee:

Report / Event	**ClinO-MD**	**Deadline**
- SAE that is not unrelated - Device deficiency with SAE potential *in Switzerland and abroad*	Art. 33	Without delay, max. 7d
Safety and protective measures *in Switzerland and EU/EEA states*	Art. 34, 36, 38	≤ 2d or ≤ 24h in case of termination or interruption for safety reasons
Annual Safety Report *with data from Switzerland and abroad*	Art. 35, 38	annually

Swissmedic information sheet:
www.swissmedic.ch/md-clinicaltrials-de

Swissethics guidance document on 'safety reporting':
www.swissethics.ch

MDCG guidances:
MDCG 2020-10/1
MDCG 2020-10/2

Safety reporting for Cat. A clinical trials

Art. 33-36 ClinO-MD

- Reporting by the sponsor to Swissmedic:

Report / Event	ClinO-MD	Deadline
Reports according to Articles 87–90 MDR (Materiovigilance)	Art. 33	According to ri…

Swissmedic Materiovigilance: www.swissmedic.ch/md-materiovigilance

- Reporting by the sponsor to ethics committee:

Report / Event	ClinO-MD	Deadline
- SAE that is related, with test procedure - Reports according to Articles 87–90 MDR (Materiovigilance)	Art. 33	- Without delay, max. 7d - Accordi…
Safety and protective measures	Art. 34, 36, 38	…of termination or interruption for safety reasons
Annual Safety Report	Art. 35	annually

Swissethics guidance document on ‘safety reporting’: www.swissethics.ch

ClinO-MD: Transitional provisions for approved trials

Art. 48 ClinO-MD

- Basically: Trials are subject to the new legislation (reporting, etc.)
- Approvals remain valid until the expiry of the approval period
- Publication of the results in approved registries according to Art. 64 para. 1 ClinO and deadline in Art. 42 ClinO-MD
- Substantial amendment requires recategorisation according to Art. 6 ClinO-MD

Outlook and further information

Outlook

- Revision of ClinO-MD: Inclusion of provisions for in vitro diagnostic medical devices, including companion diagnostics

- Links and documents

www.kofam.ch/

Swissmedic information sheet:
www.swissmedic.ch/md-clinicaltrials-de

MDCG guidance documents:
MDCG 2020-10/1
MDCG 2020-10/2
MDCG 2021-6
MDCG 2021-8

swissethics guidance document on 'Substantial modifications': www.swissethics.ch

Swissethics guidance document on 'safety reporting': www.swissethics.ch

Thank you for your valued attention