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IVDR@noon
FOPH «Round Table» IvDO 24.11.21

Summary – Assessment – Consequences

19 January 2022

Michael Bosshard, Roche Diagnostics (Schweiz) AG / Vice president SVDI

IVDR@noon

Introduction of Michael Bosshard

- Dipl. Natw. ETH (Biology)
- Executive MBA HSG in General Management
- 30 years of industry experience in the in-vitro diagnostics field

- **Roche Diagnostics (Schweiz) AG**
  Head of Sales Centralized Diagnostics
  www.diagnostics.roche.com

- **SVDI (Swiss Association of the Diagnostics Industry)**
  Vice president
  www.svdi.ch

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FOPH „Round Table“ IvDO 24.11.2021

- Summary: Participants, Agenda, Content
- Assessment
- Consequences

Summary: Participants

Authorities‘ (14) and Associations‘ representatives (6), 3 with IVD ties

Teilnehmer/Teilnehmerinnen:		
Lévy	Anne	BAG
Enderle	Matthias	BAG
Albrecht	Daniel	BAG
Egger	Jonas	BAG
Pellegrini	Alessandro	BAG
Cianci	Amedeo	BAG
Meier	Brigitte	BAG
Rinderknecht	Matthias	BAG
Pürro	Michel	Swissmedic
Lory	Simon	Swissmedic
Perritaz	Christophe	SECO
Etienne	Philippe	SECO
Heinimann	Karl	GUMEK
Schönbucher Seitz	Katharina	GDK
Driessen	Susanne	Swissethics
Delfosse	Daniel	Swiss Medtech
Bosshard	Michael	SVDI
Risch	Martin	FAMH
Kappes	Alexander	unimedsuisse
Leumann	Christian	swissuniversities

Summary: Agenda 24.11.2021

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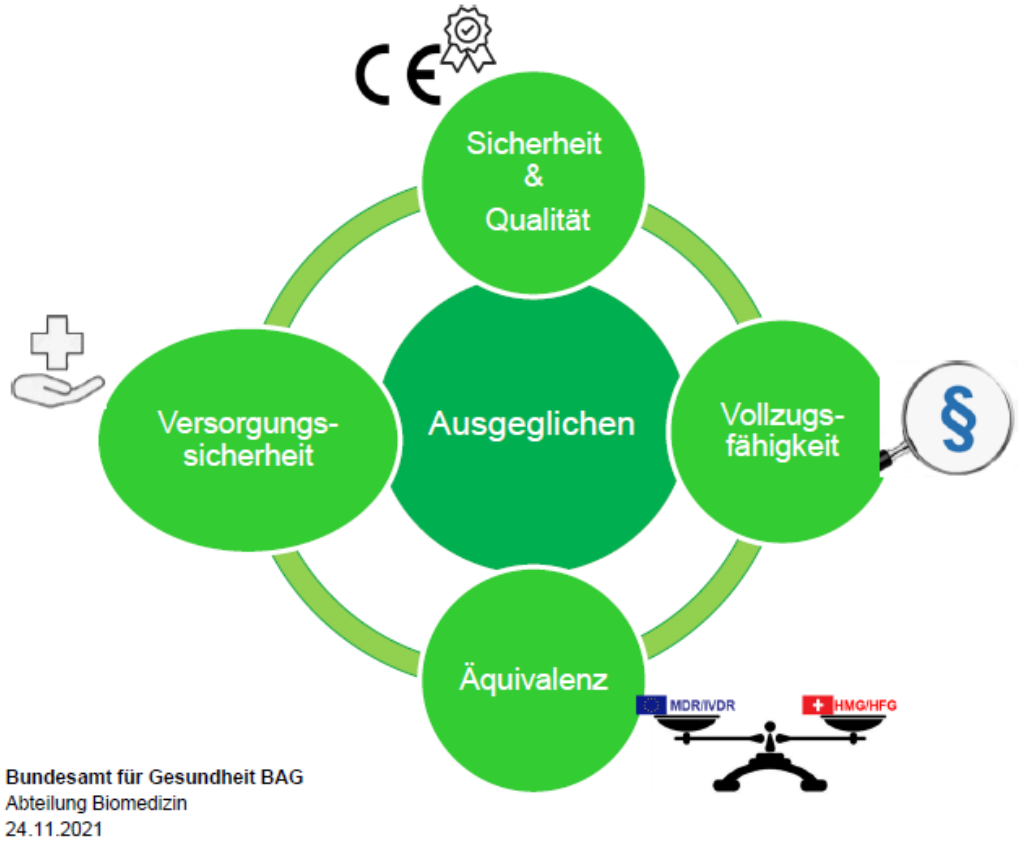
- MRA Auswirkungen und aktueller Stand der Verhandlungen
- Ausgangslage und grundlegende Begriffserklärung
- Erfolgte Auffangmassnahmen MepV
- Geplante Auffangmassnahmen IvDV
- Erfolgte und geplante Auffangmassnahmen in KlinV-Mep
- Übernahme der Übergangsfristen der IvDR in die IvDV

Summary: Content / Principle



- With IvDO, the FOPH wants to balance
  - Security & Quality
  - Executability
  - Equivalence (i.e. IVDR <-> IvDO)
  - Security of Supply
- Missing:
  - Economic Efficiency
  - Innovative Capability

Summary: Content / MedDo

Ausgangslage und grundlegende Begriffserklärung

Auffangmassnahmen:

Regelungsbereich zur Milderung der negativen Auswirkungen der fehlenden Aktualisierung des Mutual Recognition Agreement (MRA), welche sinngemäss äquivalent zu den EU-Verordnungen in der Schweiz anzuwenden ist.

Beispiel:
Registrierung der Wirtschaftsakteure bei Swissmedic, Meldungen an Swissmedic, Mandatierung eines Schweizer Bevollmächtigten, Labelling

Bundesamt für Gesundheit BAG
Abteilung Biomedizin
24.11.2021

Summary: Content / MedDo

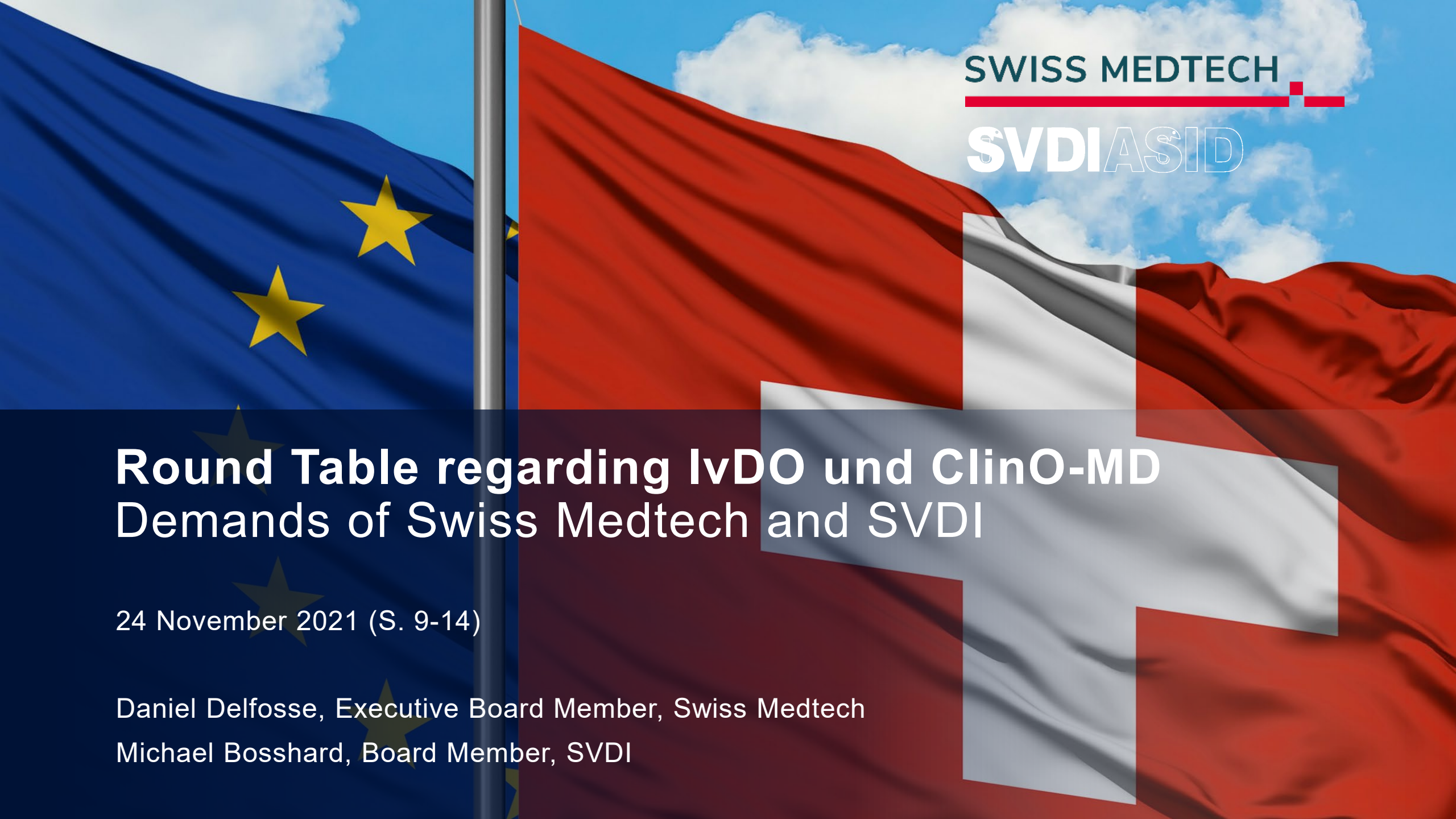
Repercussions of the missing update of the MRA (MedDo)

- No access to EUDAMED
- Exclusion of EU specialist groups
- Leads to erosion and loss of information, needed for market surveillance
  - CH-Economic Operators need to register with Swissmedic
  - CH-REP must be mandated and labbeled (transition periods)
  - Unilateral recognition of EU-conformity assessments (CE)
  - Incidents need to be reported to Swissmedic

Summary: Content
IvDO intended mitigating measures

- Principle
  - Substantive equivalence to EU-IVDR
  - Adjustments (due to MRA) analogous to MedDo where possible
  - We are in an ongoing legislative process

- Due to lack of time, there will be NO 2. consultation (!)
- IvDO shall come into force on 26.05.2022



Round Table regarding IvDO und ClinO-MD
Demands of Swiss Medtech and SVDI

24 November 2021 (S. 9-14)

Daniel Delfosse, Executive Board Member, Swiss Medtech
Michael Bosshard, Board Member, SVDI

Consultation Answer

Swiss Medtech and SVDI have firmly rejected the draft of the ordinance.

→ Procedural demands:

- Fundamental revision of the ordinances
- Adjustment to the new reality of Switzerland as a Third Country (without MRA)
- Inclusion of the stakeholders

Consultation Answer

→ Substantive demands:

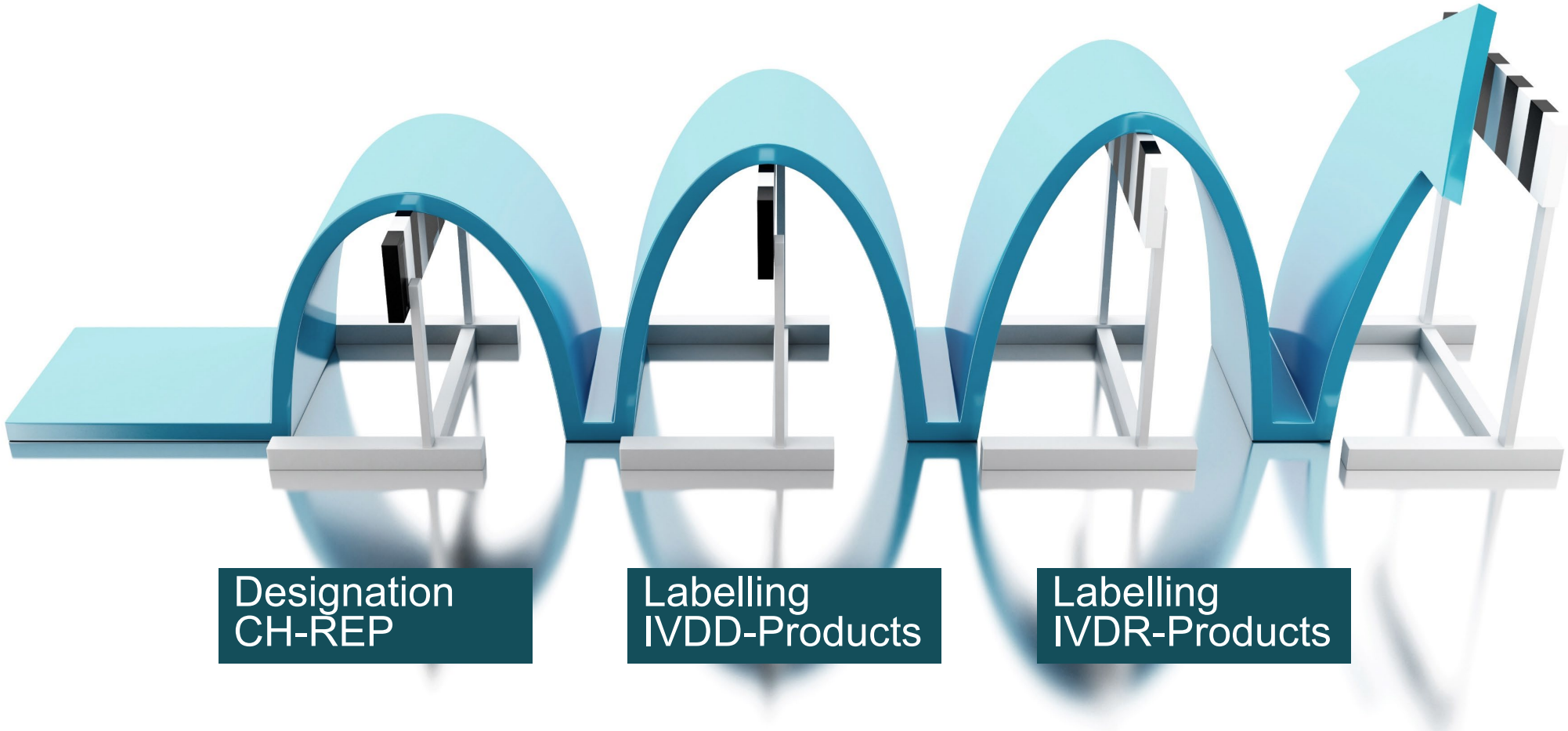
Equivalence to (current) IVDR

- Grace periods as long as the ones, the EU Commission proposed for the IVDR
- No self-imposed national restrictions to the scope of action

Goal: Security of supply

For IVDs Switzerland is even more dependent on import than for medical devices

Import hurdles



How many foreign IVD manufacturers will pass these hurdles?

Conditions for in-house tests

IVDR, Art. 5 (5c): The laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation;

If this passage is to be included in the IvDO, it ought to be considered that:

- many laboratories are accredited according to ISO 17025
- most laboratories are not yet accredited according to ISO 15189
- the accreditation according to ISO 15189 is welcomed, but only with sufficient transition periods

Quo vadis?

The revised **MedDo** complicates the import of medical devices

→ imminent supply shortage after expiration of transition periods

– Copy of the procedure for **IvDO** results in the same problems
– Main problem: Labelling of „legacy devices“ with CH-REP and Importer

→ Intensive cooperation between authority and industry representatives desired

Summary: Content / transition periods analogous to IVDR

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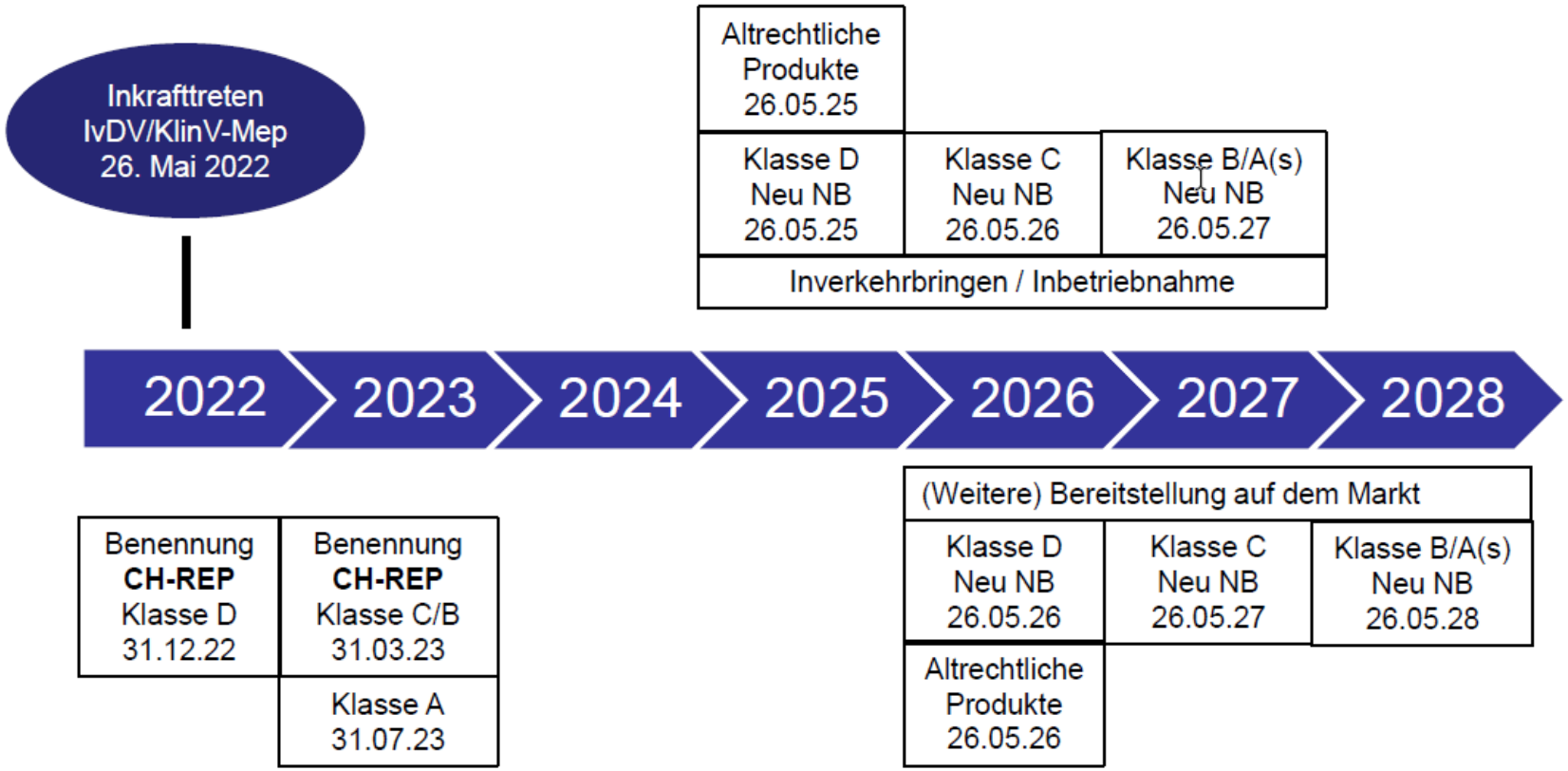
Überblick – Termine und Fristen



Bundesamt für Gesundheit BAG
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Assessment - Consequences

- MRA will not be updated in the short term: Switzerland with third-country status
- IvDO is formulated «congruently» with the EU-IVDR (analogous to MepV/MDR)
- Additional effort for economic operators
  - Registration and mandating CH-REP
  - Labelling?!
    - Enforcement chaos, supply shortages (deadlines, import hurdles)

- SVDI is therefore considering intervening so that an IvDO results which is
  - pragmatic-practical
  - moderate
  - «intelligent»
  - enforcement- and innovation-friendly

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Thank you!

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