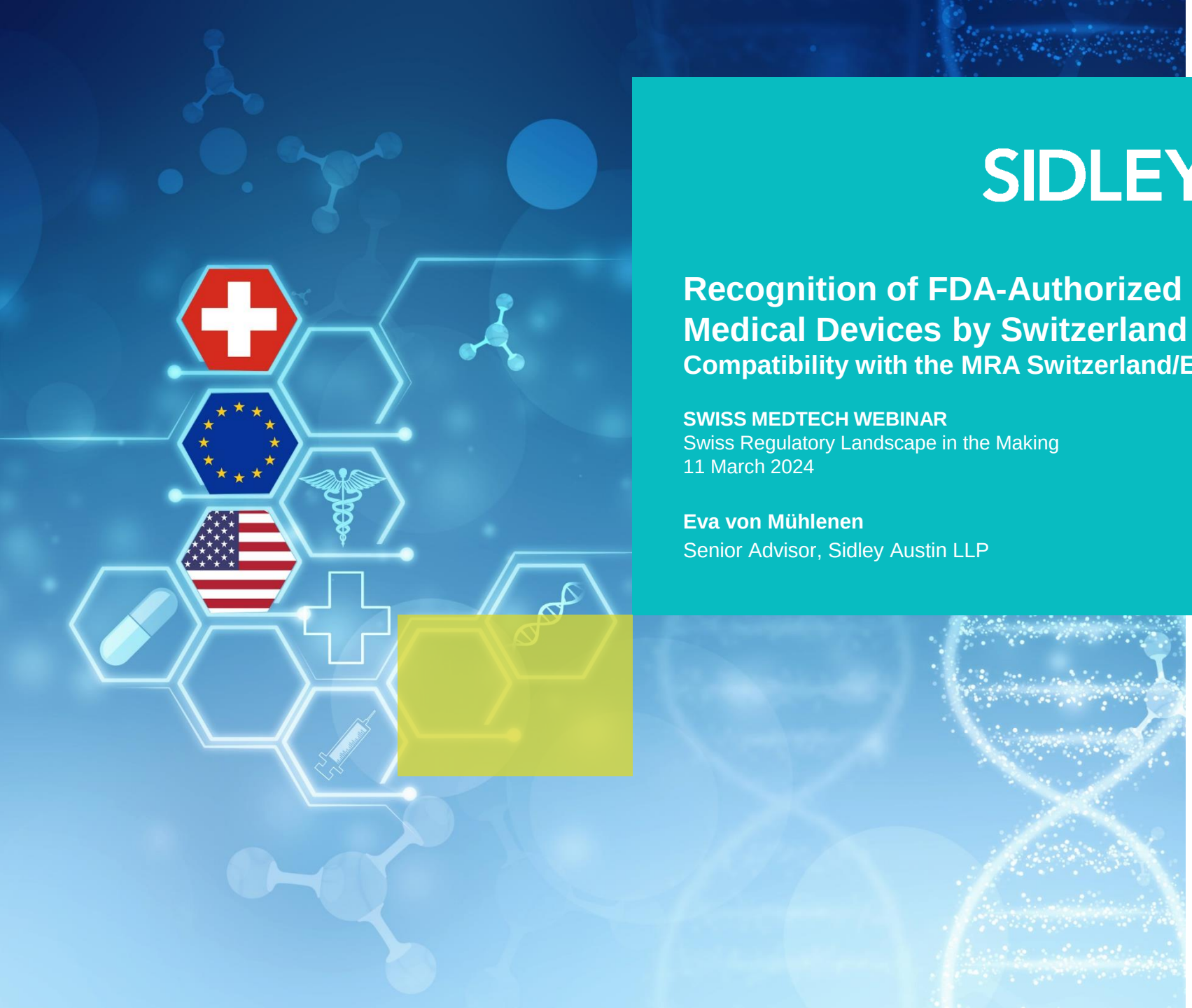

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Recognition of FDA-Authorized Medical Devices by Switzerland - Compatibility with the MRA Switzerland/EU

SWISS MEDTECH WEBINAR
Swiss Regulatory Landscape in the Making
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Eva von Mühlenen
Senior Advisor, Sidley Austin LLP

TALENT. TEAMWORK. **RESULTS.**

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Bilaterale III and Motion 20.3211 Müller

Best of Both Worlds

Bilateral III Package

- Counter-measures against the **erosion of the bilateral way**.
- **Update existing & concluding new** Single Market Agreements
- Mutual Recognition Agreement (**MRA**) as part of market access agreement.
- **Key differences:**
  - Vertical vs. sectoral approach
  - Institutional issues now dealt with individually (dynamic assumption of rights, dispute settlement)
  - No **guillotine clauses**
  - Clear constitutional process.

Motion 20.3211 Müller

- What does the **re-negotiation** mean for the implementation of Motion 20.3211 Müller?
- Recognition of US Food and Drug Administration (**FDA**) authorizations shall be **no reason** for **the EU to refuse MRA update** and re-negotiation.
- Legally, there is no reason why Switzerland could not have "**best of both worlds**".
- It must be ensured that this is clearly upheld in the **new negotiations**.

Compatibility of Recognition with MRA
No Reason to Reject the Update

Would an adaptation of the Swiss medical device regulation, according to which medical devices with FDA authorizations are eligible for the Swiss market (cumulative to the marketability of medical devices with CE marking), mean

- that Swiss regulation of medical devices would **no longer be equivalent** to that of EU?
- that an update of the MRA between the EU and Switzerland for the medical device sector **could therefore be rejected** by the EU?
- that this would lead to a **distortion of competition** in the form of unjustified advantages for Switzerland?

Compatibility of Recognition with MRA
No Reason to Reject the Update

The recognition of conformity assessments or marketing authorizations for medical devices from third countries as a basis for market access for such devices in Switzerland would

- **not affect the equivalence** of Swiss and EU medical device regulations,
- **not allow the EU to refuse** to update the MRA,
- **not lead to a distortion of competition** in the sense of an unjustified preferential treatment of Switzerland.

Recognition of FDA Authorizations
Not Affect Equivalence

The recognition of conformity assessments or market authorizations for medical devices from third countries (e.g.. US FDA) as the basis for market access for such products in Switzerland would have no influence on the equivalence of Swiss medical device regulation with EU regulation.

- **Equivalence**: **basic prerequisite** for MRA between EU and Switzerland.
- Equivalence applies to **MRA scope.**
- **Outside the scope** of application: the question of what requirements the contracting parties impose on medical devices that are authorized for sale on the respective domestic markets is **not relevant to the MRA.**
- **MRA itself:** expressly presupposes that agreements with third countries **may exist in addition to the MRA.**
- **Example of Australia:** shows that acceptance of medical device authorizations from FDA had no influence on equivalence of Australian MD regulation to EU regulation.

Recognition of FDA Authorizations
No Reason to Reject Update of MRA

From a legal point of view, there is no reason to assume that the recognition of market authorizations other than the EU conformity marking (such as an FDA approval) for Swiss market access could be a reason for the EU to refuse to update the MRA.

- Objective **of the EU-Switzerland MRA**: Eliminate trade barriers in medical products sector, aligning with the World Trade Organization (**WTO**) Technical Barriers to Trade (**TBT**) Agreement.
- **MRA Provisions**: No exclusion of third-country market authorization recognition.
- **Impact on CE-Certified Products**: Unilateral recognition of third-country authorizations does not affect the import of EU CE-certified products into Switzerland
- **Marketability in the EU**: Products from third countries marketable in Switzerland cannot enter the EU without meeting EU market access requirements.

Adjustment to Swiss Regulation
No Distortion of Competition

An adjustment to the Swiss regulation of medical devices, whereby medical devices with a market approval other than the EU conformity marking (such as an FDA authorization) unilaterally recognized for the Swiss market, would not lead to a distortion of competition in the sense of unjustified advantages for Switzerland.

- Currently: Recognition of conformity marks is limited **to the relationship EU/Switzerland.** Recognition of third country marketing authorizations is not a topic of the EU/Swiss MRA.
- **Technical regulations:** only to the extent necessary (e.g., ensure health).
- No distortion of competition by **market openings.**
- In accordance with the intention of the legislator, **coordination of several legislations must be possible.**

Compatibility of Recognition with MRA
No Reason to Reject the Update

The recognition of conformity assessments or marketing authorizations for medical devices from third countries as a basis for market access for such devices in Switzerland would

- **not affect the equivalence** of Swiss and EU medical device regulations,
- **not allow the EU to refuse** to update the MRA,
- **not lead to a distortion of competition**.

In the forthcoming negotiations, it is essential to ensure that both,

- the **updating of the MRA** with the EU and
- the **recognition of FDA-authorized medical devices** are clearly and resolutely affirmed.

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EVA VON MÜHLENEN
SENIOR ADVISOR

SIDLEY AUSTIN LLP
+41 22 308 00 12
EVONMUEHLENEN@SIDLEY.COM

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Assessing the Future Revision of Swiss Legislation
Overview & Outlook

Methodology

- Representative medical devices groups selected
- Identify regulatory differences
- Risk-based assessment of negative differences
- Bridging the gaps

Timeline

- End of 2024: Federal Council decision on key options