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MDR market surveillance of the Member States

MDR@noon – Swiss Medtech, 07/04/2021, Peter Studer

state of play - as of 26th May 2021,....

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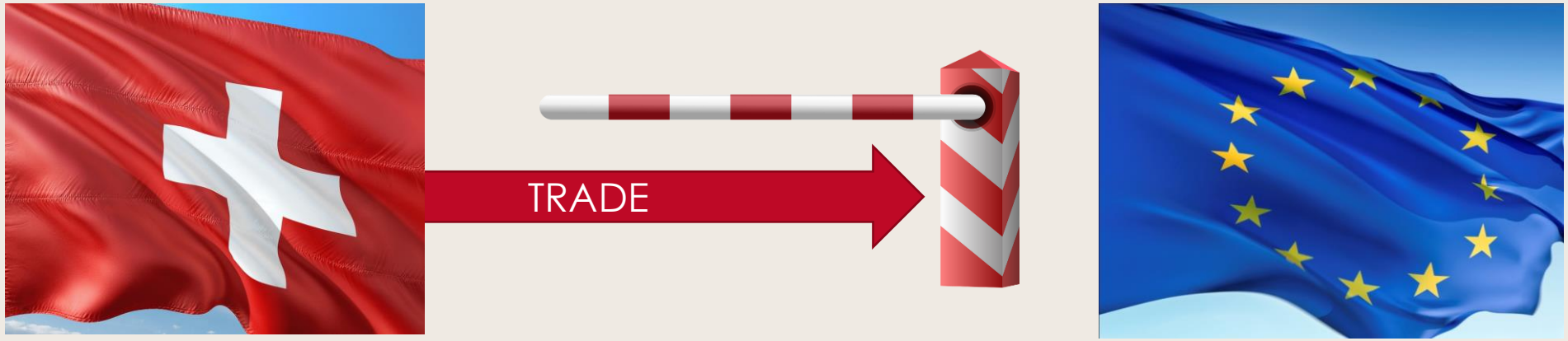
...the EU Commission's (COM) interpretation of the MRA Chapter 4



- third country status
  - to be applied to products according to (MDD, AIMDD and)[1] MDR
  - as of 26th May 2022, including products according to IVDD and IVDR
- placing on the market
  - established EAR[2] (within EU27 or EEA member states[3])
  - amended labeling (EAR and Importer)

1) Information from the Commission, 31/03/2021, https://www.team-nb.org/info-from-eu-regarding-swiss-mutual-recognition-agreement/
2) European Authorised Representative
3) European Economic Area

new requirements still in process as of DoA[1]

produced Swiss medical devices still in Swiss warehouses at DoA?

- products need to be placed on the EU market before DoA:
  - administratively delivered to an EU importer;
  - according to the COM, devices can be seen as placed on the market if they are still in a warehouse (outside the EU)[2];
  - it is key to have evidence of a transfer of ownership before DoA – read carefully the Blue Guide under 2.3[3];
    - "Placing a product on the market requires an offer or an agreement (written or verbal)…for the transfer of ownership…
    - …This transfer could be for payment or free of charge. It does not require the physical handover of the product."
- newly produced products require third country requirements as of DoA

1) Date of application, 26th May 2021
2) COM, interpretative document placing on the market medical devices, https://ec.europa.eu/docsroom/documents/10265/attachments/1/translations
3) COM, Blue Guide, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ%3AC%3A2016%3A272%3ATOC

non-conformities of third country requirements[1]

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Member States (MS) may take measures

- currently not to exclude:
  - meetings with COM / MS in Brussels (e.g., MDCG) may be used to discuss measures against non-compliant Swiss devices (according to MDD, AIMDD and MDR);
  - market surveillance activities could be conducted by national competent authorities (NCA);
  - COM could be asked by MS to coordinate further measures.
- MDR will be the guideline for market surveillance activities
  - according to section 3

1) according to the current COM's interpretation of the MRA

NCA should take in consideration

MDR distinguishes market surveillance procedures conducted by NCA

- unacceptable risks, referred to in Article 94(a)
  - "..may present….to the health or safety of patients, users or other persons, or other aspects of the protection of public health"
  - Article 95: Procedure for dealing with devices presenting unacceptable risks…
  - Article 96: Procedure for evaluating national measures at Union level (regarding Article 95)
- other non-compliance, referred to in Article 94(b)
  - otherwise (apart from Article 95) does not comply with the requirements laid down in this Regulation
  - Article 97: Other non-compliance

NCA can not ignore

non-conformities of third country requirements are not unacceptable risks

- such a market surveillance needs to be conducted according to "other non-compliance", then such a device referred to in Article 97(1):
  - does not comply with the requirements laid down in this Regulation (MDR);
  - does not present an unacceptable risk to the health or safety of patients, users or other persons, or other aspects of the protection of public health (not of the EU internal market);
  - they (NCA) shall require the relevant economic operators to bring the non-compliance to an end...
  - within a reasonable period that is clearly defined and communicated to the economic operator and...
  - that is proportionate to the non-compliance.

However

market surveillance conducted by NCA remains remains an act of national sovereignty

- despite of harmonization efforts:
  - Member Stats will tailor their program according to their needs;
  - depending on the size of the market surveillance organizations, they will be able to deal with the "other non-compliance" in different intensities;
  - depending on national needs, the interpretation of what is "appropriate to end non-compliance" (regarding Article 97(1)) will vary.
- economic operators should be prepared:
  - comprehensible document of the Swiss manufacturer with project details on the conversion of the portfolio to third country requirements;
  - define the most pragmatic way;
  - involve local law firms – if helpful.