Regulatory summit, 2022-03-31

Ur myndighetens perspektiv

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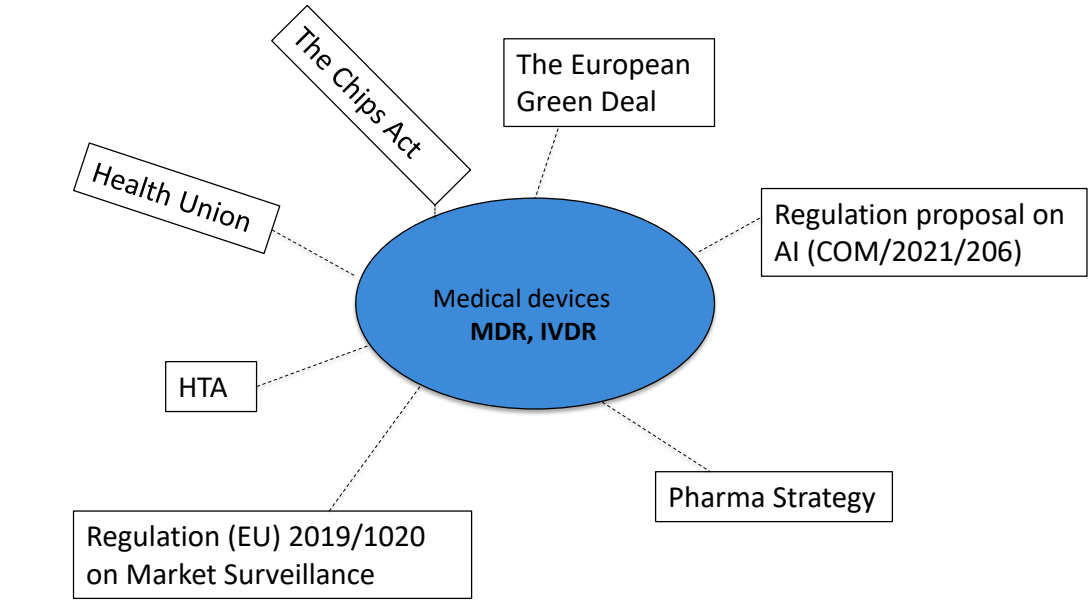
LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY



LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Changes in national regulations

- Implementation of IVDR, regulation amending IVDR
- Further implementation of MDR
  Reprocessing, Sanction fees, National Medical Information Systems (NMI)
- Implementation of regulation (EU) 2019/1020 on market surveillance

Status on ongoing work

Implementation work	Status
Implementation of IVDR in the Act on Medical Devices	Proposition(law proposal) to be approved by government before going to Riksdag
Amendment of Ordinances (2021:631) and (2021:988) due to IVDR	Government decision needed
Amendment of Ordinance (2021:631) allowing reprocessing	Government decision needed
Implementation of Regulation (EU) 2019/1020 on Market Surveillance in the Act on Medical Devices	Proposal on Lagrådsremiss to be decided by government
Amendment of Ordinance (2021:631) due to Regulation (EU) 2019/1020 on Market Surveillance	Work ongoing
Amendment of MPA regulation 2021:32 due to IVDR	Public consultation, deadline March 23
Amendment of HSLF-FS 2021:52 due to IVDR (not MPA)	Public consultation, deadline April 5
New MPA regulation on National Medical Information Systems	Public consultation, deadline March 1

National implementation of MDR and IVDR

Regulations
(föreskrifter)

- Amendment of HSFL-FS 2021:32 due to IVDR, date of application 26 May 2022
- Amendment of HSLF-FS 2021:52 due to IVDR, date of application 2022
- New Regulation on National Medical Information Systems related to MDR

Ordinances (förordningar)

Ordinance 2021:631

- Amentment to allow reprocessing, DoA XXX
- Amendment to implement IVDR, DoA 26 May 2022
- Amendment to implement Regulation (EU) 2019/1020 on Market Surveillance, DoA 25 July 2022?

Ordinance 2021:988 on fees

- Amendment to implement IVDR, DoA 26 May 2022

Acts (lag)

Act 2021:600

- Amendment to implement IVDR, DoA 26 May 2022
- Amendment to implement Regulation (EU) 2019/1020 on Market Surveillance, DoA 25 July 2022?

Amendment to Act and Ordinance on Medical Devices due to Annex XVI

MPA Regulations

Amendment of HLFS-FS 2021:32:

- Registration requirements for Swedish manufacturers and authorised representatives of IVD devices
- Requirements on vigilance reporting for IVD devices, SAE reporting under performance studies
- Requirements on in house manufacturing of IVDs
- Requiremets on clinical investigations and performance studies

Proposal for New Requirements in MPA Regulations from May 26, 2022

Registration
Manufacturers and authorised representatives of IVD devices with registered business in Sweden shall give information about their business to the Swedish Medical Products Agency before the devices are placed on the market. This information shall be given two months after entry into force at latest.

Applicable as long as EUDAMED is not fully functional.

Vigilance reporting
- Serious incidents with IVDs shall be reported to the Medical Products Agency when the incident has occured in Sweden. Applicable to both IVDR, IVDD and legacy devices.
- Field Safety Corrective Actions (FSCA) with IVDs shall be reported to the Medical Products Agency if Sweden is affected or if the manufacturer has its registered business in Sweden. Applicable to both IVDR, IVDD and legacy devices.
- Trend reports for IVDs shall be sent to the Medical Products Agency if the incidents have occured in Sweden or if the manufacturer has its registered business in Sweden.
- The Field Safety Notice for an IVD shall be given to the Medical Products Agency if Sweden is affected by a FSCA.

Applicable as long as EUDAMED is not fully functional.

Proposal for New Requirements in MPA Regulations from May 26, 2022

In house devices
Registration
Healthcare institutions with in house manufacturing of IVDs shall register its activities with IVO.

Requirements that previously existed in regulation 2008:1 have been moved to the MPA regulation. Requirements on traceability, SOPs, documentation and archive rules. Many of those requirements will cease 2024 when most of the requirements in IVDR become applicable.

Documentation requirement in article 5.5 g) in IVDR for class D devices will be applicable also to the other risk classes from 2024.

Some requirements in IVDR are applicable from 26th of May 2022
Article 5.5 (a) The devices cannot be transferred to another legal entity
Annex I

Proposal for New Requirements in MPA Regulations from May 26, 2022

Clinical investigations/performance studies

The sponsor of a clinical investigation with CE-marked devices is allowed to make exceptions for certain requirements related to the application.

SAE reporting during a performance study shall be reported to MPA (until EUDAMED is fully functional).

Regulation on National Medical Information Systems (NMI)

- New regulation necessary as the current NMI regulation is referring to the old regulation that will not be applicable anymore
- Plan to have the new regulation in place to the 26th of May
- The mandate to regulate NMI specifies that the requirements have to be the same or similar to the requirements of MDR

7 kap. Ytterligare bemyndiganden och övriga bestämmelser

Föreskrifter om lagens tillämplighet

1 § Regeringen eller den myndighet som regeringen bestämmer får meddela föreskrifter om att krav som följer av eller väsentligen motsvarar kraven enligt förordning (EU) 2017/745 och denna lag ska gälla även för produkter som inte anges i 1 kap. 2 § men som i fråga om användningen står nära sådana produkter.

Differences between MDR and proposed regulation for NMI

MDR	NMI
• Classification • Notified body • CE-marking • UDI • Clinical investigation • Clinical evaluation • Registration and vigilance reporting in Eudamed	• No classification • Self certification • NMI-marking • NMI-ID • No clinical investigation • Evaluation • Registration and vigilance reporting to Läkemedelsverket

Reprocessing

Conditions for reprocessing - when reprocessing is being allowed in Sweden

Who is allowed to reprocess medical devices?

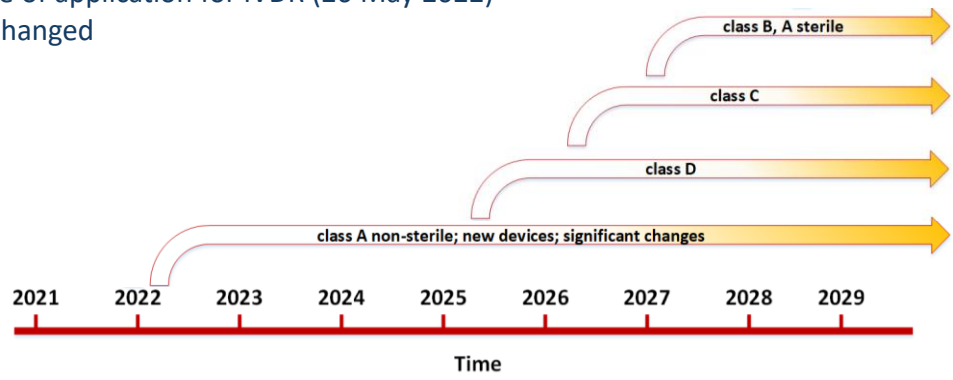
- A healthcare institution can reprocess and reuse a single use device according to article 17 in MDR.
- A healthcare institution can also require that en external reprocessor within the EU or EES is reprocessing its device, if the device in its entirety is returned to that healthcare institution.

What are the requirements?

- The requirements in MDR, article 17(3) and 17(5) shall be fulfilled
- The common specifications for reprocessing of single use devices, Kommissionens genomförandeförordning (EU) 2020/1207, have to be fulfilled. https://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:32020R1207&from=EN
- Compliance with common specifications shall be certified by a notified body.
- Reprocessors and external reprocessors that are healthcare institutions or part of healthcare institutions shall inform IVO of their activities and the devices concerned.
- Serious incidents shall be reported according to the common specifications.

Stepwise implementation of IVDR

- Proposal COM(2021)0627 adopted
- Only affecting transitional provisions
- Date of application for IVDR (26 May 2022) unchanged



Implementation of IVDR – A Summary…

Devices without certificate (IVDD)

Class	Placing on the market	Making available
Class A	26 May 2022	26 May 2025
Class D	26 May 2025	26 May 2026
Class C	26 May 2026	26 May 2027
Class B	26 May 2027	26 May 2028
Class A sterile	26 May 2027	26 May 2028

Devices with certificate (IVDD)

With valid certificate, as long as **26 May 2025**

In house manufacturing of IVDs Art. 5(5)

Annex 1 (GSPR) + (a) Transfer to another legal entity not allowed

26 May 2022

(b)-(c), (e)-(i) **26 May 2024**

(d) No equivalent device available **26 May 2028**

Article 110(3) of IVDR – legacy devices

The requirements of IVDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices placed on the market according to article 110(3) of IVDR instead of the corresponding requirements in Directive 98/79/EC.

Guidelines on ”significant change” in IVDR as well as requirements on legacy devices are planned to be published before the date of application of IVDR.

IVDR consolidated: EUR-Lex - 02017R0746-20220128 - EN - EUR-Lex (europa.eu)

Registration in EUDAMED

National registration requirement in Sweden until EUDAMED is fully functional
Voluntary to register in EUDAMED.

Fees - manufacturers and authorised representatives

- Ordinance on fees (SFS 2021:988) applicable from the 1st of January 2022
  Invoices with the new fees (30 000 SEK/year) were sent out by the end of February

The new fees can have a high impact on some companies. MPA has informed all economic operators that have to pay the fees that the deadline for the invoices has been changed to the **31st of May**. This is to give the MPA and the Ministry of Health and Social Affairs time to investigate if there are any actions that can be taken to ease the burden, especially for small companies.

De nya, högre avgifterna kan slå hårt mot enskilda företag och Läkemedelsverket har därför gått ut med information till alla medicintekniska aktörer som omfattas av de nya högre avgifterna om att förfallodatumet för fakturorna har skjutits fram till den **31 maj.**

Bakgrunden till detta är att Läkemedelsverket tillsammans med Socialdepartementet undersöker vilka åtgärder som kan underlätta för tillverkare och auktoriserade representanter, framför allt för små företag.

Newsletter in Swedish: MedTek från Läkemedelsverket (anpdm.com)