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MDR/IVDR national implementation

A summary view from selected member states

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Sciences Law Firm meeting
18 November 2022

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Agenda

- Introduction
- National interpretation of "placing on the market" and "making available" under the MDR and IVDR
- National implementing MDR and IVDR measures (e.g. sanctions for non-compliance, enforcement policy)
- National derogations under articles 59 and 97 in view of expiring MDD/AIMDD/IVDD certificates

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Introduction

- MDR and IVDR are regulations, but still leave a lot of national options
- The MDR transitional regime is becoming more and more of a problem – what about national derogations and exemptions?
- Regulatory deadlines under the MDR and IVDR depend on the interpretation of the concept of placing on the market and making available – but is that the same everywhere?

Placing on the market and making available

- The language conundrum (property right required or not?)
- Is placing on the market a two or one step process?
- Is there any specific interest of the authorities re MDR and IVDR deadlines (e.g. has customs received instructions)?

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Germany

- No differentiation between “first placing on the market” and “any subsequent placing on the market” anymore

France

- MDR => *ordonnance* 04/20/2022
- IVDR => *ordonnance* 07/29/2022
- *Still missing some regulatory texts*

- Some relevant guidelines from ANSM : https://ansm.sante.fr/documents/reference/reglementation-relative-aux-dispositifs-medicaux-dm-et-aux-dispositifs-medicaux-de-diagnostic-in-vitro-dmdiv/faq-reglement-dm-4eme-partie#questions_generales

No specific French rules regarding :

- placement on the market
- making available on the market
- putting into service

Greece

- Not implementing MDR or/and IVDR - no applicable legislation in Greece - so far
- Ministerial decisions YA 130648/2009, YA 3607/2001, YA 130644/2009 based on previous Directives (MDD/IVDD/AIMDD) - still in force
- “Placing on the market” and “Putting into service” = the terms used for Greek MDs
- No harmonization with the current MDR/IVDR terminology

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Italy

- Italian implementing legislation merely refers to the MDR with regard to placement on the market, making available on the market, putting to service (section 4 of Legislative Decrees 137/2022 and 138/2022)

- → No specific national rules

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Belgium

- No specific national rules

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The Netherlands

- No specific national preferences
- Dutch authorities religiously follow MDCG guidance

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Spain

- Lack of clarity
- Making available: Only if transfer of property? Or also transfer of possession or any other right (*as in Spanish version of Blue Guide*)
- Essential definition for transitional period under art. 120(4) MDR
- Spanish regulatory authorities no final position yet with respect to art. 120(4) MDR
- For medicinal products “effective commercialization in Spain” (*which needs to be communicated to Spanish authorities and needed to avoid application of sunset clause*) requires transfer of ownership

UK (NI + GB)

- MDR applies in Northern Ireland
- Great Britain implements MDD
- Blue Guide doesn't bind – but is influential
- In GB, PotM is **explicitly reserved** to an entity established in GB (Manufacturer, UKRP or importer)

National implementing measures

- MDR and IVDR leave considerable room for implementation, e.g.
  - Sanctions (article 113 MDR)
  - Reprocessing regime (article 17 MDR)
  - In-house produced devices regime (article 5 (5) MDR and IVDR)

  - Where are the member states on implementing legislation?

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Germany

- Establishment of own database for Germany (DMIDS) until December 31, 2022 (shall be compatible to EUDAMED)
- Detailed catalogue of sanctions (administrative fines and imprisonment up to 10 years); illegal devices can be confiscated

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France

- Sanctions - Dual nature :
  - Administrative = ANSM sanctions/penalties up to 1,000,000 euros – *interesting ANSM guidelines : ansm.sante.fr*
  - Criminal : up to 1,875,000 euros + 5 years prison
- Reprocessing of single use MD is forbidden
- In-house produced devices regime : no specific regime apart from declaration to be made to the “ARS” / ministry of defense

Greece

- MDD/IVDD/AIMDD Regime
- EOF audits and imposes fines (privately): art. 19 LD 96/1973, art. 175 MD 32221/2013 – similar provisions to medicines; size of the sanctions depends on the type of infringement, persons held liable for, the repeatability - up to €100.000
- Unspecified regime for reprocessing MDs
- No specific policy yet about devices which are produced in-house.

Italy

- Sanctions range from EUR 20,000 to EUR 150,000, considerably increasing subjects and sanctionable cases (art. 27 of 137/2022 and 138/2022): mostly against the manufacturer, but also against sponsor of a clinical investigation or PRRC
- In-house produced devices regime: vigilance powers of MoH and power to impose limitations
- Reprocessing regime has not been regulated by the Italian lawmaker, therefore the reprocessing of single-use devices is not allowed

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Belgium: reprocessing SUD

- Article 12 Law of 20 December 2020 (in effect since 26 May 2021):

- confirms the principles of reprocessing of SUD as laid down in article 17 MDR

- further regulates that healthcare institutions that reprocess MD and use reprocessed MD within their institution must notify themselves on the FAMHP website + must communicate the following information (*cf.* Royal Decree of 12 May 2021 - in effect since 26 May 2021):

  1) their name and address
  2) the contact details of a contact person
  3) where appropriate, the name, address and contact details of a contact person of the external reprocessor who reprocesses the devices at the request of the healthcare institution
  4) the original UDI-DI of the device, if applicable
  5) the name of the original manufacturer
  6) the original trade name of the device
  7) the description of the device
  8) the declaration of conformity referred to in article 5(5)(e) MDR (the declaration to be drawn up and made publicly available by the health care establishment indicating the name and address of the health care establishment / device identification data / declaration of conformity with the general safety and performance requirements of Annex 1 MDR) + the certificate issued by the notified body, demonstrating compliance with the Common Specifications for Reprocessing (cf. article 17(5) MDR)

Belgium: reprocessing SUD

- Reprocessing is prohibited for (Royal Decree of 12 May 2021 in implementation of Article 17, 9 MDR):

1. devices emitting radiation and devices necessary for their administration;
2. devices used for the administration of cytostatics or radiopharmaceuticals;
3. devices incorporating medicinal substances;
4. devices that pose a risk of transmission of spongiform encephalopathy;
5. implantable devices;
6. devices that operate with batteries or accumulators that cannot be replaced or that pose a risk of failure after reprocessing;
7. devices with an internal memory required for their use that cannot be replaced or that presents a risk of malfunction after reprocessing

Belgium: hospital use exemption

In addition to the rules on the hospital use exemption laid down in article 5 MDR: art 7 Law of 20 December 2020 + art 3 - 5 Royal Decree of 12 May 2021 provide as follows:

- As to the declaration referred to in article 5, § 5, e) MDR (conformity with the general safety and performance requirements of Annex 1 MDR) to be drawn up and to be made publicly available by healthcare institution:
    - it must be published via the application available on the FAMHP website
    - It must include:
        - name and address of the manufacturing health institution
        - the details necessary to identify the devices:
            1) the identification of the device within the healthcare facility
            2) the description of the device
            3) the nomenclature code referred to in Article 26 of MDR
            4) the device classification according to the rules defined in Annex VIII MDR
            5) the intended use of the device
        - a declaration that the devices meet the general safety and performance requirements set out in Annex I MDR/IVDR and, where applicable, information on which requirements are not fully met with reasoned justification

Belgium: hospital use exemption

- Serious incidents occurring during the use of a device referred to in article 5(5) MDR + corrective actions referred to in article 5(5), first subparagraph, (h) MDR:
  - shall be notified to the FAMHP using the form available on the FAMHP website
  - the notification shall be made within the time limits stipulated in art 87, §§ 2 to 5 MDR
  - upon request, healthcare institutions shall provide to the FAMHP any document allowing the verification of the conformity of devices and of the vigilance system of those
- The manufacturing and use in health care institutions of implantable devices + devices emitting ionizing radiation = prohibited

  + the King may, for reasons of public health, restrict the manufacturing and use in healthcare institutions of a specific type of devices

Belgium: sanctions

- In execution of article 113 MDR: article 85 Law of 22 December 2020 on medical devices + article 84 Law of 15 June 2022 on IVD medical devices: sanctions of 5 levels:
  - Level 1: fine of € 26,- to € 500,- (x8)
  - Level 2: fine of € 50,- to € 5.000,- (x8) and/or imprisonment of 8 days to 1 month
  - Level 3: fine of € 200,- to € 50.000,- (x8) and/or imprisonment of 1 month to 1 year
  - Level 3: fine of € 200,- to € 50.000,- (x8) and/or imprisonment of 1 month to 1 year
  - Level 4: fine of € 1.000,- to € 100.000,- (x8) and/or imprisonment of 1 year to 3 years
  - Level 5: fine of € 2.000,- to € 200.000,- (x8) and/or imprisonment of 2 years to 5 years

Belgium: sanctions

- Level 1: fine of € 26,- to € 500,- (x8)
  - obligation for manufacturer to implement and keep up to date post-market surveillance system
  - safety obligations regarding parts and components
  - obligation for manufacturer to have statement accompanying custom made device and keep available to particular patient
  - healthcare institution's obligation to provide info to FAMHP regarding conformity and vigilance of medical devices manufacturerd under hospital use exemption
  - obligations for distributors/importers regarding information and quality when changing labels/packaging

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Belgium: sanctions

- Level 2: fine of € 50,- to € 5.000,- (x8) and/or imprisonment of 8 days to 1 month
  - rules on claims with regard to the device's intended purpose, safety and performance
  - information requirements and implantation card to be supplied to patient with implanted device
  - manufacturer's obligations regarding submission of technical documentation and EU declaration of conformity, designation of authorised representative, etc.
  - obligation for authorised representative to immediately inform competent authority/notified body when mandate terminates
  - healthcare institution's obligations regarding hospital use exemption
  - general obligations for importers
  - monitoring, assessment and other obligations of notified bodies
  - rules for sponsors and healtchare practitioners with regard to clinical investigations
  - information and documentation obligations for distributors
  - mandatory format and mandatory content of agreement when manufacturer changes notified body
  - any use of a medical device contrary to the requirements of the MDR or the Law

Belgium: sanctions

- Level 3: fine of € 200,- to € 50.000,- (x8) and/or imprisonment of 1 month to 1 year
  - requirements for medical devices in order to be made available/put into service
  - obligations related to reprocessing of single use devices
  - obligations related to systems and treatment packages
  - identification obligations in supply chain (traceability requirement)
  - impediment of inspections
  - rules on clinical evaluation and clinical investigation
  - general obligations of manufacturer, economic operators, healthcare institutions
  - notified bodies (notification by notified body when designation is suspended or revoked; consultation procedure for clinical evaluation devices class III and IIb; obligatory withdrawal of certificate in case of change of notified body, etc)
  - requirements concerning conformity application, plan and safety report post-market surveillance, periodic safety report and serious incident analysis and field safety corrective actions
  - prohibition to manufacture certain devices under the hospital use exemption

Belgium: sanctions

- Level 4: fine of € 1.000,- to € 100.000,- (x8) and/or imprisonment of 1 year to 3 years
  - requirements for notified bodies, subsidiaries and subcontracting
  - measures imposed by FAMHP (corrective measures, preventive health protection measures, measures related to products presenting an unacceptable risk to health and safety) to economic operators, sponsors, investigators

Belgium: sanctions

- Penalty can be increased with one level if the violation:
  - was committed with fraudulent intent
  - caused a serious undesired accident
  - was committed by a person abusing the trust related to his profession
  - was committed through large-scale dessimination processes (internet)
  - was committed as part of a criminal or terrorist organisation
  - constitutes recidivism within a period of 5 years

- Punishable attempt to commit a violation = punished with the minimum penalty applicable to the violation itself

The Netherlands

- Sophisticated sanctioning guidelines (aka the ‘pinball machine’) that produce a fine based on a large number of weighted factors
- Courts normally endorse the santioning guidelines as such, some discussion possible about choices made in application
- No specific policy about in-house devices yet – authorities are waiting for MDCG document
- ‘Strict’ regime for reprocessing with additional national provisions

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Spain

- Under preparation: New Spanish Law on Medical Devices adapting to MDR/IVDR.
- Expected to be approved end 2022 – first quarter 2023
- Local policy:
  - In-house medical devices (*only in hospitals*)
  - Reprocessing of single-use medical devices
    - list of devices that cannot be reprocessed
    - only hospitals or entities with license to manufacture
    - requirements for performance of reprocessing, commercialization of reprocessed devices
- Sanctions: very serious breach under Spanish law from 90k to 1mill+
- Enforcement authorities national and regional – inspection plans to be expected

UK

- Powers to:
  - seize devices and records
  - prohibit sales
  - impose **unlimited fines**
  - commence criminal proceedings (up to 6 months imprisonment)
- No detailed sanctioning guidance
  - MHRA tends to reserve sanctions for extreme conduct
- No special rules on reprocessing or on custom-made devices

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National derogations

- Any article 59 derogations granted? What is the process?
  - What is required for application? Timing?

- Any article 97 (1) measures taken? What is the process?
  - What is required for application? Timing?

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Germany

- BfArM considers Art. 59 MDR as a rule for exemptional cases
  - “restrictive interpretation”: only applicable if no other device/therapy is available for patient treatment
  - Not applicable if there are only economic grounds
- Art. 97 (1) is subject to interpretation by regional competent authorities (65 in Germany!);
  - Guidance by Federal Ministry of Health (April 2022) that Art. 97 (1) could be applicable for cases where certification is delayed.
  - Local competent authorities may tolerate delayed certification (downside: no approval)

France

- article 59 derogations will be granted by ANSM
  - Awaiting for regulatory texts for the process

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Greece

- MDD/IVDD/AIMDD Regime
- Derogations foreseen in order to protect public health and decided by EOF (National Organization for Medicines)
- For placing on the market and putting into service
- By a duly justified application with no specific forms or timelines.

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Italy

- Authorizations pursuant to §59 MDR:
  - within 60 days from application
  - application by manufacturer or by hospitals, also for single patients'
  - exceptions are few, but at least one has been granted; process: confirmation by hospitals that derogation is in the interest of public health or patients safety
- No deviating national measures on §97 (1) MDR

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Belgium: article 59 derogations

- Regulated in art 26 Law of 22 December 2020 + art 9 Royal Decree of 12 May 2021

- Request for article 59 derogation to be justified and submitted through a standard form on the website of FAMHP with following information:
  - reasons justifying the request
  - the period for which the derogation is requested
  - description of the medical device
  - wether a derogation has been granted/requested in a third country/other member state
  - whether the conformity assessment procedure was initiated
  - contact details of the applicant
  - if applicable, contact details of the patient for whom the request is filed

  + any document requested by the FAMHP with regard to this information
  + any document justifying that the request is in the interest of public health or patient safety or health

Belgium: article 59 derogations

- Ministry of Health can grant the derogation (= authorisation to place the medical device on the market/put it into service) taking into account the following criteria:
  - absence of any alternative on the market (= any other device/product/treatment that can achieve a similar goal)
  - the expected benefit must be significant, compared to available alternative product/device/treatment

- Ministry of Health informs the Commission and the other Member States of any decision to authorise the placing on the market/putting into service of a device under such a derogation where such authorisation is granted for use other than for a single patient

Belgium: article 97 measures to address non-conformity

- Not regulated in Belgian national law – but some guidance on website FAMHP
- Request to be submitted with the FAMHP
- Conditions to be fulfilled during the "authorised" period of non-conformity:
  - no serious incident/no risk of serious incident of materiovigilance that calls into question the benefit-risk balance of the medical device established in its clinical evaluation report
  - the placing on the market must be exclusively limited to existing Belgian customers
  - the obligation to inform the customers of the non-compliance and derogatory situation
  - the manufacturer must ensure that the devices supplied under this derogation fully, and without exception, comply with the requirements applicable when the corresponding CE-certificates were still valid
  - obligation to keep the FAMHP updated of any progress/news from the notified body regarding the conformity assessment procedure

The Netherlands

- Ministry of Health decides after advice competent authority
- No specific forms, contact point or timelines
- Decisions are not published
- Good contact at competent authority indispensible

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Spain

- Possible alternative to manage situations after end of transitional periods ¿?
- Issues:
  - How to apply (lack of clear process, absence of clear requirements, need to convince authorities, etc.)
  - Who should apply
  - When to apply
  - Lack of predictability (previous experience not so good)

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UK

- Can apply for temporary derogations *in the interests of the protection of health*
  - MDD language
- Examples of use:
  - Manufacturers orphaned by NBs
  - Many derogations during the pandemic
- Guidance for applicants exists
  - e.g. monthly reporting to MHRA
- No MDR-specific guidance for NI

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Any other national developments of note?

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France

Clinical investigations:

- Extensive modifications of the French regulations on clinical research => MDR + specific national rules:
- Some guidelines:
- https://ansm.sante.fr

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Greece

What to expect when you are expecting…

https://elblogdeidiomas.es/en/difference-between-hope-and-expect/

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Greece

- In Greece, MDR/IVDR implementation has been delayed!
- GDPR Adoptive Law has been issued in 2019 by Law 4624/2019 with a lot of grey areas that still need to be defined - BUT the national DPA has started to impose heavy fines.
- Legislative measures are needed ASAP, since previous certifications progressively begin to expire.
- Lagging behind from some EU Members with regards to implementation, we collaborate with SEIV, the leading Association of Health – Research & Biotechnology Industry in Greece established in 1986 in order to aid Government departments with MDR/IVDR implementation.

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Italy

- Medical devices' companies who sell to the Public Administration face the imminent prospect of stellar payments due to Italian Regions.
- About 40% of excess spending of each Region will need to be reimbursed by private companies on the basis of their turnover.
- Set-off with payments by hospitals.
- Several challenges have been filed in Court.

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The Netherlands

– Surprise competent authorities inspections of authorised representatives over the next three months

– Surprise inspections of mobility products manufacturers for MDR compliance

UK

- GB will introduce a new regulatory framework in July 2024 (**UK MDR 2024**)
  - Substantially aligned with MDR and IVDR
  - Lengthy transitional periods and unilateral recognition of CE Marks
  - Possibility of rubberstamping FDA approvals
  - Interim approvals of **Innovative Devices** (Pathway for Innovative MedTech)

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