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~ WIDELY RESPECTED LIFE SCIENCES BOUTIQUE ~ CHAMBERS EUROPE 2017

EU MDR AT THE HALFWAY POINT OF TRANSITION

Axon Lawyers seminar
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health
food
technology

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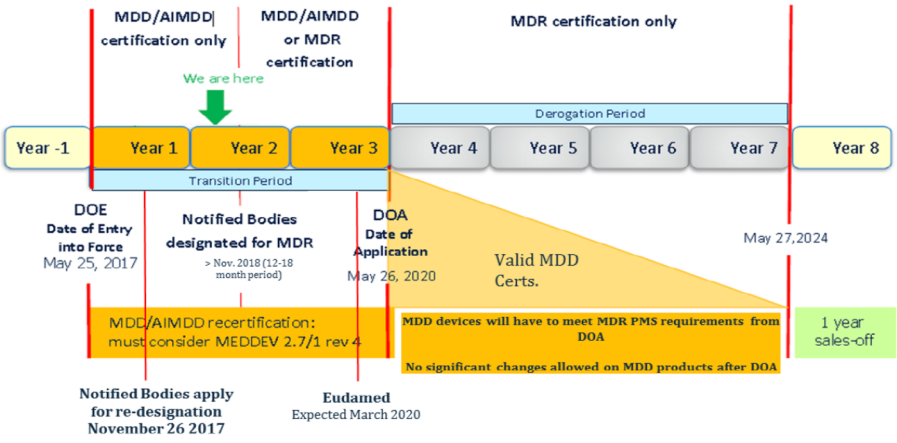
Overview

- Where are things at the halfway point of the transitional period?
  - Implementation machine seems to be stalling
  - NL implementation of MDR and IVDR
  - Bottlenecks
  - Brexit

"How did it get so late so soon? Its night before its afternoon. December is here before its June. My goodness how the time has flewn. How did it get so late so soon?"
~Dr. Seuss

Transitional regime recap



MDR / IVDR EU implementation machine seems to have stalled

Implementation machine seems to have stalled

- CAMD Roadmap is not being delivered on apart from limited FAQs
- No Common Specifications – not even the necessary ones
- No implementing acts yet – not even the necessary ones
- It seems we are at a point where everything that could be readily agreed on has been agreed – now the laborious process of rule development is starting

Implementation machine seems to have stalled

- Commission and member states position:
  - MDR has all the law you need, rest is nice to have detail – work with what is there
  - If the bare necessities implementation is done just before 26 May 2020 we have done our job

Netherlands proposal for implementation act is in the works

Tweede Kamer der Staten-Generaal **2**

Vergaderjaar 2018–2019

35 043 **Regels over de veiligheid en kwaliteit van medische hulpmiddelen (Wet medische hulpmiddelen)**

Nr. 2 **VOORSTEL VAN WET**

Netherlands proposal for implementation act is in the works

- No significant extra burden expected (on top of MDR and IVDR direct requirements)
- Council of State pointed to a loophole for devices reprocessed in other member states in EU

Nederland wil de nieuwe regelgeving lastenluw implementeren. Daarom zijn er keuzes gemaakt om bepaalde onderwerpen niet in de Nederlandse wetgeving op te nemen terwijl de verordening hiertoe wel de ruimte laat. De verordening biedt bijvoorbeeld de mogelijkheid om nationale bepalingen in te voeren voor de registratie van distributeurs. Nederland neemt dit niet over in de regelgeving en zal geen extra registratieplicht opleggen aan distributeurs. Ten aanzien van het aanmelden van klinisch onderzoek betekent dit wetsvoorstel ook een beperking van de administratieve last ten opzichte van de huidige situatie. Klinisch onderzoek moet in de huidige situatie apart worden aangemeld bij de CCMO en bij de Inspectie Gezondheidszorg en Jeugd. In de nieuwe situatie kan de fabrikant via de Europese databank (Eudamed) elektronisch een aanvraag indienen voor de beoordeling van het klinisch onderzoek of de prestatie-studie. Tot slot moeten partijen kennis nemen van de nieuwe Wet medische hulpmiddelen. De inschatting is dat hier een minimale tijdsinvestering voor nodig is.

Het voorstel is voor advies voorgelegd aan het Adviescollege Toetsing Regeldruk (ATR). Het college stelt vast dat de eisen en verplichtingen volgen uit de EU-verordeningen en rechtstreekse werking hebben, waardoor zij volgens het Handboek Meting Regeldruk niet in het kader van dit wetsvoorstel in beeld hoeven te worden gebracht. Naar het oordeel van ATR neemt dit niet weg dat fabrikanten door de scherpere eisen en scherper toezicht (dat volgt uit de verordeningen) merkbaar meer regeldruk zullen ervaren. Voor deze ontwikkeling vraagt ATR dan ook de bijzondere aandacht van de Minister. ATR concludeert tot slot dat de wet geen extra regeldruk oplevert ten opzichte van de regeldruk die al uit de verordeningen voortvloeit. In dit kader wijst het college op de bevindingen van de sectorscan innovatieve medische hulpmiddelen van de rechtsvoorganger van ATR.[3]

NL implementation act is more punitive than current law

- Misleading information provision / advertising (art. 7 MDR / IVDR) criminal offense
- Recidivism of hospitality provisions (*gunstbetoon*) criminal offense
- Pretty steep penalties foreseen (up to 10% of last year's turnover), for device compliance infringements e.g.
    - Infringement of general compliance, clinical evaluation and GSPR requirements
    - Infringement of hospital produced devices provisions
    - This will be a departure from the current IGJ penalty policy with its top penalty of € 900.000
- Costs of surveillance to be passed on to industry
- Infringement of informed consent in device trials criminal offense

Artikel 14 Bestuurlijke boete

1. Onze Minister is bevoegd tot oplegging van een bestuurlijke boete van ten hoogste het bedrag dat is vastgesteld voor de zesde categorie, bedoeld in artikel 23, vierde lid, van het Wetboek van Strafrecht of, indien dat meer is, ten hoogste 10% van de omzet van de onderneming, in het boekjaar voorafgaande aan de beschikking waarin de bestuurlijke boete wordt opgelegd, ter zake van een gedraging die in strijd is met:

Bottlenecks

- Notified bodies – designation process
    - Not many notified bodies applied at the first opportunity
    - MDR accreditation uncertain due to unpredictable MDR notification timelines
    - MDR scope of designation dependent on staffing issues at notified bodies – count on some notified bodies not being able to support the scope they applied for
    - Overly formalistic and messy approach in joint assessments for MDR – notified bodies are frustrated about black box approach by JAT
    - First notified body applicant for MDR and IVDR accreditation has just withdrawn its application

Bottlenecks

Notified bodies – capacity and soft transition

- MDR certification timelines uncertain due to capacity issues at notified bodies
- MDD and AIMDD recertification deadlines moved forward
- Notified body oversight process and extent of surveillance for soft transition period unclear

Bottlenecks

- Competent authorities and Commission
  - Process of issuing of SRNs for Eudamed interaction is not known
  - Timelines for obtaining SRNs uncertain
  - Staffing of MDCG structure for scrutiny requires massive resource mobilisation
  - Commission has lost crucial expertise over the years
  - Inexperienced staff at competent authorities and Commission is issue - experience and expertise behind implementing the rules is missing

Brexit

- At present, uncertain whether no deal Brexit or not and if deal what it will look like
    - Most MFRs do not have a solid Brexit plan in case of hard Brexit
- Regardless of tentatively optimistic negotiations member states caution companies to prepare for no deal scenario
    - Plan be can be ramping up production to build bridging stock

#Brexit preparations

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES

Brussels, 10 January 2018

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF INDUSTRIAL PRODUCTS[1]

- Consequences for economic operators (unless the instrument between UK and EU provides differently) in case of 'hard' Brexit because UK is no longer "Union" so
    - Manufacturer in UK is not in Union, needs importer and AR for EU
    - Importer and AR for EU purposes cannot be based there
    - UK can not / no longer have notified bodies
        - For current directives (AIMDD, MDD, IVDD)
        - For MDR and IVDR
        - Transition to EU27 NB before withdrawal date (29 March 2019)
    - All CE certificates granted by UK notified bodies will be invalid in the EU per withdrawal date because European law ceases to apply and UK notifications of notified bodies become void
    - Unsure if CAMD orphaning procedure applies to this

Some consequences

- Hospitals are already reporting less and less devices available as manufacturers terminate supply due to portfolio rationalization
    - Mobilize hospitals
    - Mobilize specialist HCP associations
    - Mobilize patient associations
- Manufacturers are increasingly reluctant to participate in large tenders towards end of transitional period as result of insecurity of timely CE marking, which will compound problems for hospitals and for patients

Million dollar question: extension of deadlines MDR?

- MedTech Europe and COCIR have started a concerted lobby given the bottlenecks
- Commission and member states see bottlenecks as a commercial problem since the regulatory system is ready and robust enough in their view
- There is no regulatory precedent for this – Radio Equipment Directive for example also had a big bottleneck at the end and EU did not amend deadlines
- Shortages of medical devices are very unpopular politically, especially if politicians have been publicly warned for them
- European Parliament has been the champion of the patient and is now silent

Possibility of national exemptions

- The MDR does not contain exemptions to its transitional regime
- Competent authorities may however apply exemptions for non-compliant devices on their market, e.g. when due to bottleneck manufacturer does not obtain MDR CE certificate timely
    - These exemptions apply on national level
    - Authorities have limited resources to grant and monitor them
    - Possibility to lobby for CAMD guidance on certain national procedures, like orphaning procedure currently developed

Interpretation of transitional regime

- Interpretation of crucial terms, like ‘significant change’
    - Concept of ‘significant change’ is enormous problem for ongoing manufacturing site rationalization projects after acquisitions
    - CAMD could provide legacy product friendly interpretation in guidance
- Amount of clinical evidence that can be postponed to PMCF phase

Orphaning solution

- There will be three big orphaning occurrences during which a lot of manufacturers will loose their notified body:
  - Brexit – in case of hard Brexit (29 March 2019)
  - Date of application and around (notified bodies that did not apply for MDR and are too busy to re-issue MDR cert)
  - Soft transition certs are expiring of the notified bodies that did not make the cut for MDR
- CAMD approach needed to deal with orphaned devices and manufacturers
  - CAMD could cooperate to develop a similar policy for cases in which shortage of NB capacity causes manufacturers to miss out on timely certificate(s)
  - Member states already have this discretion for their own jurisdiction

Economic operators regime difficult for everybody

- MFRs have trouble understanding new economic operator rules and related aspects
  - Centralisation of new regulatory roles – allowed or not? If so how?
  - Liability of AR and PRRC
  - Qualification of actors in supply chain is difficult – fulfillment houses particularly problematic
  - Remediation is problematic with third parties (independent distributors and ARs)

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KEEP CALM AND CALL AXON

THANKS FOR YOUR ATTENTION

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