What does the EU legislation on sustainable corporate governance and supply chain due diligence mean for medical technology companies?

Medline's perspective

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- The European Parliament's Resolution on due diligence and its annex (draft Directive text) dated 10 March raise the prospect for industry collaboration to comply with regulatory requirements

- What might this look like for MedTech Europe members in practical terms?

Paragraph 22 of the Resolution on due diligence
"…coordination at sectoral level could enhance the consistency and effectiveness of due diligence efforts, allow for the sharing of best practices and contribute to levelling the playing field"

Article 11 of the draft Directive text (annex to the Resolution on due diligence)
"1. Member states may encourage the adoption of voluntary sectoral or cross-sectoral due diligence action plans at national or Union level aimed at coordinating the due diligence strategy of undertakings.

Undertakings participating in sectoral or cross-sectoral due diligence action plans shall not be exempt from the obligations provided for in this Directive."

1. Medline proposal for MedTech Europe: A community of practice on supply chain due diligence

Objectives:

- Member-driven knowledge sharing and exchange on ethical sourcing

Highlights:

- Document library on ethical sourcing
- Webinars or face-to-face meetings

Potential focus areas:

- Supply chain mapping – tier 1 and beyond
- Due diligence measures – risk profiling, audits, grievance etc
  - Human rights vs environment vs governance
- Resources and capacity building for implementation

2. EU Regulation vs EU Directive on supply chain due diligence

EU Regulation:

- Single legislative instrument directly applicable across the EU
- Predictable and consistent
- MedTech Europe members could support each other in:
  - Identifying relevant enforcement authorities and their approach and practices at EU or country level

EU Directive:

- Must be transposed into national legislation by Member States
- Some degree of fragmentation inevitable
- MedTech Europe members could support each other in:
  - Keeping track of legislation per country as it is approved
  - Comparative analysis of legislation, including reporting requirements
  - Identifying relevant enforcement authorities at EU or country level

3. Medline proposal: MedTech Europe to issue periodic news updates (e.g. quarterly newsletter)

Objectives:

- To keep members informed of regulatory developments, media reports etc

Potential topics:

- Status of legislative proposals at EU level and by member states
- Updates on emerging best practices
- Media coverage of relevant topics e.g. enforcement actions by regulators
- Decisions and actions by MedTech Europe CSR Board Task Force

4. Directors' duties and obligations (sustainable corporate governance)

Possibility that supply chain due diligence and SCG will be combined into one legislative proposal

Medline suggestions for potential areas for MedTech Europe members to collaborate on:

- Similar to supply chain due diligence e.g. community of practice, monitoring enforcement and reporting requirements, news updates, possible alignment with Non-Financial Reporting Directive

As assessed by Medline, the advantages of keeping due diligence and SCG separate include:

- They raise separate issues, requiring different interventions by different teams/departments within companies
  - Same applies to enforcement authorities in Member States
- Separation allows for more targeted debates and stakeholder input