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Time Running Out To Comply With New EU Sustainability Legislation

by Tom Gallen

At a webinar organized by the Association of the European Self-Care Industry, sustainability expert Onur Durmus, partner at ERM, gave an overview of the Corporate Sustainability Reporting Directive and what consumer health companies must do to ensure compliance.

[Editor's Note: *This article originally appeared in [HBW](#), Medtech Insight's sister publication covering consumer the consumer health products industry.*]

Consumer health companies large and small will soon be required to make detailed disclosures on environmental, social, and corporate governance (ESG) topics under new European Union legislation.

As the EU pushes ahead with its target of reducing greenhouse gas emissions by 55% by 2030, it is widening the scope of its sustainability reporting requirements in a move which will significantly increase the number of eligible companies.

Currently, large “public-interest entities,” such as EU-listed firms and banks employing over 500 people, are required to publish an annual statement on ESG performance under the Non-Financial Reporting Directive (NFRD).

Around 12,000 companies come within the purview of the NFRD, but from 2025 this legislation will be superseded by the Corporate Sustainability Reporting Directive (CSRD) which will extend ESG reporting requirements to a total of 50,000 businesses operating in the EU.

Designed to increase transparency of companies’ sustainability reporting, the CSRD covers more than 1,000 disclosure requirements across governance, strategy, risks, opportunities and impacts.

A separate but related piece of legislation, the Corporate Sustainability Due Diligence Directive, will require companies to identify across their whole supply chain any adverse impact on the environment and human rights.

The introduction of the CSRD and CSDDD will have consequences far beyond the borders of the EU, according to Onur Durmus, EMEA service leader for sustainable operations at sustainability consultancy ERM.

“It’s about not just regulating the internal market, but also looking at having an impact on the external market,” Durmus told a webinar organized by the Association of the European Self-Care Industry.

The requirement to examine the environmental impacts of the whole supply chain will see EU companies interacting with partners around the world in gathering and exchanging data and pushing for good practices, Durmus said, and in effect creating a “sustainability information habitat.”

In the years to come, the introduction of the European Single Access Point Database will give companies and individuals access to sustainability-related disclosures made by all in-scope EU companies.

With the ESAP it will be possible to rate companies on their ESG performance and targets, Durmus noted. Companies seen to be underperforming could come under criticism from both shareholders and consumers. Durmus suggests legislators may use these data as justification for more stringent regulations to ensure national and EU sustainability targets are met.

Which Companies Need to Comply?

Focusing his presentation on preparing companies for compliance with the CSRD, Durmus pointed out that the legislation is “sector agnostic.” Any EU firm that meets at least two of the requirements must comply:

- More than 250 employees
- Turnover of more than €40m
- Balance sheet of more than €20m
- Listed small and medium companies
- Non-EU based companies generating more than €150m in revenues within the EU and at

least one subsidiary or branch in the EU

The CSRD requires large companies not in scope of the NFRD to begin reporting in 2026, while listed SMEs have until 2027 and eligible non-EU companies until 2029 to file on the previous year's activities.

EU Taxonomy

The CSRD necessitates reporting in line with the EU Taxonomy Regulation, which acts as a classification system for sustainable economic activities. A relevant economic activity for consumer health companies could be the manufacture of pharmaceuticals or medical devices.

“The taxonomy is like a dictionary,” Durmus said, “you can look up what sustainable medical device manufacturing means in the eyes of European legislators.”

The first question a company needs to answer is whether its activities are eligible under the EU Taxonomy, Durmus advised.

All turnover generating activities must be reviewed. Durmus offered the hypothetical example of a company manufacturing medical devices, leasing real estate and operating a wastewater plant.

The economic activities that have been identified as eligible have to be further screened to determine if they are Taxonomy aligned, i.e., if they:

- Substantially contribute to at least one environmental objective
- Do no significant harm to any other environmental objective
- Comply with minimum social safeguards

The environmental objectives listed in the Taxonomy are:

- Climate change mitigation
- Climate change adaptation
- Sustainable use and protection of water and marine resources
- Transition to a circular economy

- Pollution prevention and control
- Protection and restoration of biodiversity and ecosystems

“The substantial contribution and doing no significant harm are also concepts that are in the regulation itself, and there are definitions for those in terms of thresholds and criteria within the Taxonomy per individual economic activity,” Durmus noted.

The third part of the alignment exercise is to look at the minimum social safeguards. Durmus summarized this as ensuring an eligible activity is in compliance with the OECD guidelines for multinational enterprises and with the International Labor Organization conventions on social and labor issues.

The final step in the process is disclosure. Companies must report all Taxonomy eligible key performance indicators by turnover, capital expenditure and operating expense.

“This whole process is quite complicated because it is linking sustainability data with financial data,” Durmus said. “So if you talk to sustainability people within your organization, they may not understand the financial flows. If you speak with financial departments, they would likely feel they lack an understanding of sustainability.”

ESRS Requirements

In addition to the disclosures required under the EU Taxonomy, to fully comply with the CSRD companies must also report sustainability data specified by the European Sustainability Reporting Standards (ESRS).

To ensure sustainability reports are comparable and reliable, the ESRS sets out 12 standards on cross-cutting, environmental, social, and governance topics.

Each topic has sub-topics, and in some cases sub-sub-topics, all of which have disclosure requirements and related KPIs. Reporting areas include governance and strategy, as well as metrics and targets.

Using the concept of double materiality, the ESRS requires companies to make disclosures on how their activities affect people and planet and how their sustainability performance and targets impact their finances.

ESRS 2 – “General Disclosures” – is mandatory, while all other standards require companies to report only what is material for their business model across their value chain and own activity.

As a result, the information to be reported under the ESRS will be different for each company.

“ESRS is the most complicated sustainability reporting standard globally, ever. And it is set to develop further with sector specific standards and fine tuning,” Durmus said.

“It's not just going to be some numbers like quantitative KPIs, but it's also going to be about governance and strategy, about target setting. For example, ‘this is my impact, and this is where I want to be by a given year.’”

“The major difficulty here is interpreting some of those requirements under the ESRS because they are just written in a very general way. Then it's about internally deciding to what level of depth you want to go and how you want to report it.”

From Discovery To Reporting

Durmus cautioned that going from the discovery phase of what must be disclosed in line with the ESRS to actually filing a report under the CSRD is a time consuming process. It takes around two years to ensure readiness for broad ESG disclosure, according to ERM's CSRD 5-phase process, which covers operational efficiency to product differentiation and risk mitigation (see image).

The journey: Meeting new disclosure obligations while creating ESG value

ERM's CSRD 5-phase process is designed to go beyond broad compliance with ESG regulatory reporting, to optimize value at every step of the journey. From operational efficiency to product differentiation and ESG risk mitigation, our phased approach enables clients to differentiate in a modular but cohesive fashion. This approach paves the way for broad ESG disclosure readiness.



ERM

Source: ERM

When companies are ready to report, they must obtain limited assurance of compliance with ESRS and their double materiality assessment process. As well as complying with this legal obligation, Durmus advised firms to consider how information is communicated to stakeholders.

“The reporting phase is not just about putting some numbers out there. It's advisable, especially for consumer facing businesses, to tell your story. ‘This is

where we are today. And we would like to transform to become this tomorrow. These are the actions that we will take and these are our goals and targets.’”

With the CSRD requiring large companies not in scope of the NFRD to begin reporting on 2025 data, Durmus said time is running out to ensure compliance. “If the organizations that you represent haven't started yet, this is really about one of the last moments to begin.”