



PERSPECTIVES

**Crosscurrents:
EU REACH, EMA &
Product Stewardship
for Sustainability**

Our perspectives feature the viewpoints of our subject matter experts on current topics and emerging trends.

PRODUCT STEWARDSHIP AS A LEVERAGE FOR SUSTAINABILITY GOALS

Approaching new drug development with life cycle management in mind provides companies with an excellent opportunity to meet both product stewardship requirements and sustainability goals. When developing robust sustainability goals, companies may incorporate information originally generated as part of product stewardship and drug approval obligations.

WHAT IS EU REACH?

The European Union's (EU) Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation governs product stewardship. Among several obligations, REACH includes a chemical safety assessment (CSA)—including a persistent, bioaccumulative, and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment—for all substances which is reported in a chemical safety report. The underlying scientific efforts are led by toxicologists.

WHAT IS THE EMA?

Similarly, the evaluation and authorization of medicinal products is conducted by the European Medicines Agency (EMA). Data submitted by pharmaceutical companies on the toxicological profile of the product allows for the assessment of potential risks to human health and the environment. The EMA toxicological evaluation includes an assessment of the product's active ingredients, as well as any excipients or impurities, to determine their potential toxic effects. The data on the product's metabolism, distribution, and excretion in the body, as well as any potential interactions with other substances or drugs, are also evaluated.

As toxicology is involved in both the REACH and EMA protocols, the author has called upon Bruce Kelman, DABT, ATS, ERT and Clara Chan, MSc, DABT to help illustrate the intersection between product stewardship and sustainability and how companies may utilize the regulatorily-driven data from product stewardship activities to improve or augment sustainability goals.

SUSTAINABILITY GOALS IN THE UK

To begin the discussion, it is important to understand that companies have great flexibility in establishing sustainability goals. Certain environmental, safety, and governance (ESG) reporting is mandatory in the UK.¹ However, there is not 100% alignment between company established goals and ESG reporting. In contrast, both EMA and REACH are nondiscretionary and well defined. Because of the flexibility of corporate sustainability goals, EMA and REACH can become functional components of sustainability. Companies, in identifying their sustainability goals, routinely include the reduction of environmental impacts of their products, improving resource efficiency, and promoting sustainable practices. These goals can be aligned with product stewardship efforts, including EMA and REACH obligations, to ensure that products are designed, produced, and disposed of in a sustainable manner.

INTERPLAY OF EMA AND REACH

REACH aims to ensure the safe use of chemicals in the EU. It requires companies to register information on the properties and uses of chemicals they produce or import into the EU and to take steps to manage any risks associated with their use. REACH is primarily concerned with the safety of chemicals and their impact on human health and the environment.

EMA, on the other hand, is responsible for the scientific evaluation and regulation of medicinal products for human and veterinary use in the EU. It evaluates the safety, efficacy, and quality of medicinal products and makes recommendations on their authorization for use in the EU.

¹ Stewart, S. UK: ESG Comparative Guide. Available from <https://www.mondaq.com/uk/corporatecommercial-law/1231990/esg-comparative-guide>. E-Pub Date: October 14, 2022.; the guide provides an excellent summary of the current status of various UK ESG/sustainability requirements.

When a new drug is being developed, the advocating pharmaceutical company must provide data to both REACH and EMA. The company must register any chemical substances used in the drug with REACH, providing information on properties and potential risks. The company must also submit a dossier of data to EMA, which includes information on the safety, efficacy, and quality of the drug.

EMA may consult with REACH during the evaluation of a new drug to ensure that the chemicals used in the drug are safe for their intended use. EMA may also consider any restrictions on the use of the chemicals imposed by REACH when making a recommendation on the authorization of the drug. In addition, EMA and REACH may share information and collaborate on areas of mutual interest, such as the safe use of chemicals in medicinal products.

The information generated through REACH CSAs, EMA approvals, and related toxicological assessments are excellent metrics for sustainability. Life cycle assessments (LCAs), for example, can be used to identify improvement opportunities, create metrics for tracking and analysis, and drive improvements to environmental impacts. Those same LCAs can be used to inform product design and development, which subsequently reduces product stewardship costs and reflects how sustainability efforts should also include a profit consideration. It is helpful to remember that sustainability is the management of three “Ps”—people, planet, and profit.

Understanding Product Stewardship and REACH

REACH establishes procedures for collecting and assessing information on the properties and hazards of substances used by various companies across many sectors within the European Union. The Candidate List of substances of very high concern (SVHCs) for Authorisation under the REACH Regulation is a major initiative for the development and transition to less hazardous chemical use by companies striving for sustainability. A study on the socioeconomic

impacts of REACH authorization conducted by ECHA found the Authorization requirement resulted in many companies reducing their use of SVHCs and seeking safe and sustainable alternatives.² In addition, the European Commission adopted its Chemicals Strategy for Sustainability in 2020 in which its goal was to create a “toxic-free environment” by driving innovation toward safer and more sustainable alternatives. It aims to “better protect citizens and the environment” and “boost innovation for safe and sustainable chemicals.” The plans of the Strategy include 1) banning the use of “the most harmful chemicals” (such as carcinogens, mutagens, reproductive toxicants, endocrine disrupters, and persistent and bioaccumulative chemicals) in consumer products and only allow their use if it is essential; 2) phasing out the use of per- and polyfluoroalkyl substances (PFAS) in the EU unless their use is essential; and 3) promoting the EU’s supply and sustainability of “critical chemicals” (such as raw materials, intermediates, or active pharmaceutical ingredients used to produce pharmaceuticals). The Strategy is part of the European Commission’s Green Deal for zero pollution.^{3,4}

Understanding Product Stewardship and EMA

EMA has scientific guidelines on the Environmental Risk Assessment (ERA) report that accompanies the marketing authorisation application for human medicinal products. The guideline describes how companies should assess the potential risks of their human medicinal products to the environment from use, storage, and disposal based on their respective environmental bioaccumulation and persistence potential. Emissions into the environment from the manufacturing or production of pharmaceuticals are not covered.^{5,6} The EMA published a draft revision of its ERA guideline in 2018 but a finalized copy has not been released at present.⁷

² European Chemicals Agency (ECHA). Socio-economic impacts of REACH authorisations. A meta-analysis of the state of play of applications for authorisation. Report No.: ECHA-20-R-14-EN, April, 2021.

³ European Commission. Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. Brussels, Belgium: October 14, 2020.

⁴ European Chemicals Agency (ECHA). Chemicals Strategy for Sustainability. Helsinki, Finland 2023. Available from: <https://echa.europa.eu/hot-topics/chemicals-strategy-for-sustainability>.

⁵ European Medicines Agency (EMA). Guideline on the environmental risk assessment of medicinal products for human use. Report No.: CPMP/SWP/4447/00, London, England: June 1, 2006.

⁶ European Medicines Agency (EMA). Environmental risk-assessment of medicines. London, United Kingdom 2015. Available from: https://www.ema.europa.eu/en/documents/leaflet/environmental-risk-assessment-medicines_en.pdf.

⁷ European Medicines Agency (EMA). Guideline on the environmental risk assessment of medicinal products for human use. DRAFT. Report No.: EMEA/CHMP/SWP/4447/00 Rev. 1, November 15, 2018.

Sustainable Products

There is growing interest in sustainable product design, which seeks to minimize the environmental impact of products throughout the products' life cycle. Toxicologists should consider how products can be designed to reduce toxicity and environmental impact, as there is growing opportunity to contribute to corporate sustainability goals. This could include advice regarding the use of safer chemicals, reducing packaging, designing products to facilitate repair and recycling, and improving waste management options to reduce environmental impact.

One of the well managed sustainability programs we have an opportunity to work with starts with a baseline assumption: "Do no harm." In discussions with the corporate leadership about the program, "do no harm" just made sense to them. It was clear from the boardroom to the production floor exactly what the expectation was for every company activity. Clarity is critical if sustainability is to permeate day to day operations. "Do no harm" fulfills all three "Ps" and sets a floor for improvements. Perhaps more importantly, it gives the people within the company a good sense of purpose and a bit of comfort as they conduct day-to-day operations with that focus. Sustainable products ("do no harm" products) meet those same three "Ps"—no harm to people, no harm to planet, and no harm to the company profits.

Sustainable products, those that result from strong product stewardship programs, drive profits. By marketing sustainability, companies benefit through increased share, pricing premiums, and reputational advancement. All three serve to drive profits. Sustainable value chains and operations improve resource management and reduce environmental costs/impacts which improve profits. Similarly, sustainable products are highly sought in the marketplace and provide an avenue for growth.

In the "People" component, good products are better received by the consumer and build pride in the company work force. Remember, REACH makes chemical data publicly available and facilitates public comment and review of that data (think NGOs). That process promotes public trust in products as a result. EMA follows a similar public review which promotes public trust in medicinal products. These regulatory processes have a positive impact on the "People" component in numerous ways.

Those same products do no harm to the planet, resulting in fewer costs through their life cycle. In combination, profits are better when costs are lower and sales are higher. Higher profits mean better reception in the overall marketplace and better access to capital. An appropriate sustainable product strategy flows into overall better corporate performance.

LEADING THE WAY: STEPS TO LEVERAGE PRODUCT STEWARDSHIP FOR SUSTAINABILITY GOALS

During the development of corporate sustainability goals, even before materiality determinations have been made, it is important to include product stewardship program information in the development discussion. Because product stewardship provides measurable data, the inclusion in the overall corporate sustainability goals can make the sustainability program more robust, more data driven, and more impactful. ESG reporting, particularly when departing from climate-driven reporting, tends to lack numerical drivers, and relies more on soft science.

First, develop a compliant product stewardship program. With strategies to minimize the environmental impact of products throughout their life cycle, product stewardship programs are ideal components of overall corporate sustainability programs. Second, identify components within the product stewardship program that fits your company's overall sustainability goals and repurpose those components with a view toward sustainability metrics. Third, remember that EMA, REACH, and related regulatory programs include stakeholder engagement obligations. Inputs from stakeholders are just as important in sustainability programs as product stewardship. Be sure to leverage good stakeholder engagement across both platforms. Finally, develop a reporting framework to track all these components. Systems such as the Global Reporting Initiative (GRI) or the Sustainability Accounting Standards Board (SASB) provide excellent frameworks for reporting on sustainability performance.

PLUG AND PLAY OPPORTUNITIES FOR SUSTAINABILITY FROM EXISTING PRODUCT STEWARDSHIP EFFORTS

Regulation mandated environmental risk assessments (ERAs) can identify potential risks to the environment, such as the toxicity to aquatic organisms or the potential for antibiotics to promote antimicrobial resistance. ERAs can help identify and mitigate potential environmental risks. ERAs can be leveraged into existing sustainability programs to reflect the efforts made to reduce impacts to the environment. For sustainability purposes, these create a good reportable data set for the company that can be tracked and reported on with substantial backup data.

Leverage regulatory-driven stakeholder engagements. Open lines of communication with regulatory agencies, shareholders, NGOs, and other stakeholders create opportunities to tell the “do no harm” sustainability story. Establishing “do no harm” as the expectation on both sides of any discussion will lead to better and more sustainable results. One of the author’s colleagues describes the sustainability process as “being better” as a result of sustainability efforts. Stakeholders appreciate open lines of communication, and companies benefit tremendously in reputational gains as a result.

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