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The complexities of ESG product compliance obligations for the life sciences industry

Whilst environmental and social governance ("ESG") issues and related concepts are increasingly mainstay product compliance requirements to bring products to market in Europe, the life sciences industry continues to grapple with the unique challenges it faces when seeking to navigate, and apply, these broad-brush product compliance requirements to life sciences products specifically:

- Whilst life sciences safety regimes are ordinarily separate from the mainstay product safety regulations in order to account for the particular aspects and risks of these types of products, these ESG requirements are not similarly tailored and, in theory, apply to all product categories in a way that does not account for the specific features of the products.

- More stringent product safety requirements are in place for the more highly regulated life sciences industry, that are necessary and foundational to ensure patient safety, and are sometimes at odds with newer ESG requirements.

In light of the importance of ESG requirements both from an ethical and legal standpoint, those in the life science industry in Europe will have to give additional thought to their own practices.

Whilst ESG requirements exist throughout the whole product lifecycle, the below areas are arguably the most problematic for the life sciences industry.

Product life cycle stage	Legislation	Issue
Design and manufacture	**The EU Ecodesign Directive and UK implementing legislation, the Ecodesign for Energy-Related Products Regulations 2010 (as amended)** underpin the legal framework governing energy-consuming products and set minimum mandatory requirements for the energy efficiency of certain products. This legislation seeks to bring all products produced or sold in the EU and UK in line with technical standards for sustainability. It requires manufacturers to reduce the energy consumption of their products by establishing minimum energy efficiency standards. It covers over 40 product groups, including boilers, lightbulbs, and televisions. **The UK Ecodesign for Energy-Related Products and Energy Information Regulations 2021**, which came into effect in July 2021, introduces eco-design and energy labelling requirements for certain energy-related products to ensure consistency between Great Britain, Northern Ireland and the EU. The Regulations also aim to lower the environmental impact of energy related products by decreasing their energy-usage and carbon footprint. **The EU Sustainable Products Initiative ("the SPI"), adopted by the EC on 30 March 2022**, includes a proposal for a regulation to expand the scope of the Ecodesign Directive, extending requirements and extending products under the Directive to those other than energy-related products e.g. electronics, textiles, furniture, steel, cement & chemicals. The SPI aims to make products placed on the EU market more sustainable.	Some electronic medical devices may be required to have a constant power supply (i.e. CPAP machines or otherwise), such that the proposed requirements within this legislation would create safety issues. Medical devices are neither expressly included, nor excluded, from the scope of the EU Ecodesign Directive or the Ecodesign for Energy-Related Products Regulations 2010. In the absence of any express exclusion provision, life sciences companies may wish to ensure that their products comply with these important pieces of legislation. In contrast, the Ecodesign for Energy-Related Products and Energy Information Regulations 2021 is clearer in that it expressly excludes medical displays which are, or form part of a medical device within the meaning of regulation *2(1) of the Medical Devices Regulations 2002 (as amended)*. The energy efficient design of medical imaging equipment such as x-rays, ultrasounds and MRIs, is expressly called for in a 'Self-Regulatory Initiative on EcoDesign of Energy using Products for Medical Imaging Equipment' ("SIR") presented in 2008 – and updated in 2012 – by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), which represents the Radiological and Healthcare IT industry in Europe. COCIR's SIR is a growing initiative and seeks to achieve the same objectives as the EU Ecodesign Directive and fulfil certain criteria.

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		The Inception Impact Assessment published by the EC which sets out the aims and objectives of the EU's Sustainable Products Initiative does not give any indication as to whether the EU Ecodesign Directive will be extended to expressly apply to medical devices. However, in anticipation that it may be extended to include medical devices, as a matter of caution, life sciences companies may wish to start considering the sustainability of existing product lines and also products that will be placed on the EU market in the future.
Advertising and labelling	**The EU Ecolabel** is voluntary, which means that producers, importers and retailers can choose to apply for the label for their products. It is awarded to products and services meeting high environmental standards throughout their life-cycle: from raw material extraction to production, distribution and disposal. The label allows consumers to recognise high quality eco-friendly products and encourages companies to develop products that are durable, easy to repair and recycle. England, Wales and Scotland (but not NI) no longer participate in the Ecolabel Scheme and so any EU Ecolabel licences awarded by the UK competent body are no longer valid in GB. Therefore, companies can no longer use UK-licensed EU Ecolabel markings on products, packaging or marketing. **The EU Energy Labelling Regulation 2017** is the key EU legislation for energy-related products in the EU and applies to all products placed on the EU market for the first time (so not including products available for a second or more time) including second hand imports. It requires an energy labelling system on a scale from A to G for efficiency. The system also requires suppliers to have a digital product database that makes it easier for regulators and consumers to check that the energy information is correct. The scheme applies to suppliers, which means the manufacturer established in the EU, its EU authorised representative where it is not established in the EU, or the importer who places a product on the EU market. The UK Government body, the Energy Saving Trust, has produced the equivalent in the UK, with tighter requirements for an A grade.	Although advertising and labelling are arguably not central to life sciences product categories, they remain relevant. The requirements in respect of labelling for energy-saving properties, as above in respect of the eco-design laws, pose specific problems for electronic medical devices that require constant power supply and whose proper functionality is contingent upon this for safety reasons.
End of life and repairability	A company can no longer simply ensure that a product is compliant when it is placed on the market and then wash its hands of responsibility. Instead, it must maintain its ESG related responsibilities throughout the lifespan of a product. The establishment of **'The Right to Repair'** as voted in by the EU Parliament in November 2020 with a view to saving costs for consumers and facilitating the development of a circular economy, means new washing machines, hairdryers, refrigerators and televisions sold in EU countries must be repairable for up to 10 years. In addition to EU contract laws providing consumers with a right to have faulty products repaired during and/or after the period provided under the legal guarantee, the EU Ecodesign Directive require the availability of spare parts for a certain period of time. The EU Ecolabel also provides for repair-related requirements.	These 'right to repair' laws are problematic and have caused concerns regarding safety issues across all impacted industries. However, the life sciences industry may, again, be disproportionately impacted in that the safety of medical devices is often contingent on shorter use of some or all components of the product (i.e. for sterility purposes or otherwise).

Product life cycle stage	Legislation	Issue
	Similarly, in the UK, the **Ecodesign for Energy-Related Products and Energy Information Regulations 2021** – also sometimes referred to as **'the Right to Repair Regulations'** – introduced in July 2021 to tackle waste, obliges manufacturers to make spare parts available for dishwashers, washing machines, washer-dryers, dryers, fridges, freezers and televisions within two years of launching a new model. These spare parts must remain available for up to 10 years. It also provides 'professional repairers' with access to spare parts and technical information.	
Waste management	The EU and UK have put in place a regime of rules relating to packaging design and waste management of packaging. **The EU's Packaging and Packaging Waste Directive ("PPWD")**, first introduced in 1994, covers all packaging placed on the European market regardless of the sector or material used. The PPWD sets targets that Member States must meet by 2025 and renewed targets in 2030 in the form of percentages on the weight of packaging that must be recycled. These vary by material, with paper and cardboard having a target of 75%. It also encourages the use of reusable packaging and systems to ensure that the return, reuse or collection of used packaging or packaging waste is the most appropriate waste management practice. In an attempt to ensure that producers bear the responsibility of the waste stage of a product's life, by 2024, producers will be obliged to finance, and at times organise, the return and/or collection of used packaging and/or packaging waste and ensure it is disposed of, reused or recycled appropriate. The standards of such schemes are set by the Waste Framework Directive, with a view to incentivising producers to design more environmentally friendly products, by setting modulated fees for placing packing on the market. The schemes feature in many countries across the world, and the UK's consultation on a 'Waste Prevent programme for England' in 2021 called for this to be taken further and place the full cost of managing waste packaging on producers. The EU's **Waste Framework Directive ("WFD")** presents a hierarchy laying down some basic waste management principles and the priority for these. The WFD and the Amending Waste Framework Directive 2018 set the overarching legislative framework for handling waste. It includes a hierarchy setting the order of preference for dealing with waste and delivering the best overall environmental outcome, as well as introducing the principles of the 'polluter pays' and 'extended producer responsibility'. The hierarchy is based on: – Prevention; – Preparing for re-use; – Recycling; – Recovery; and – Disposal. In the UK, the WFD requires businesses to confirm they have applied the above hierarchy when transferring waste, in the form of a declaration.	There is ambiguity as to the position of medical devices within key pieces of waste legislation in the EU/UK. Whilst there is an acknowledgement by the life sciences industry that recycling of products may not be appropriate for medical devices, as there are provisions to allow the legislatures to make separate legislation on these products, no such laws have yet been created, such that industry players continue to remain unclear on their obligations. It is also well recognised that some medical products are, necessarily, single use plastic products, and again there are no allowances in respect of these product categories within this legislation.

Product life cycle stage	Legislation	Issue
	The stated aim of the **Directive on waste, electrical and electronic equipment 2012 ("WEEE Directive")** is to protect the environment and human health by: (i) preventing or reducing the adverse impacts of the generation and management of waste from electrical and electronic equipment; and (ii) by reducing overall impacts of resource use and improving the efficiency of such use in accordance with Articles 1 and 4 of the Waste Framework Directive, i.e. increasing the re-use and recycling of products, resulting in a reduced amount of waste, electrical and electronic equipment being sent to landfill, thereby contributing to sustainable development. The **EU's Single-Use Plastics Directive 2019** attempts to tackle the 10 single-use plastic items most commonly found on Europe's beaches, and is promoting sustainable alternatives. The **UK's Circular Economy Package 2020** introduced a revised legislative framework, identifying steps for the reduction of waste and establishing an ambitious and credible long-term path for waste management and recycling. **UK Plastic Packaging Tax** – The UK has introduced a plastic packaging tax whereby, from 1 April 2022, manufacturers or importers of plastic packaging products into the UK may be liable under Part 2 of the Finance Act 2021 to pay a tax on those products.	The WEEE Directive was initially introduced in 2002 and required manufacturers of electronic equipment, including medical devices, to ensure that such products were appropriately and correctly discarded by users. It also set targets for the collection, recycling and recovery of products. The repealing WEEE Directive, published in 2012, imposed new obligations on manufacturers and more ambitious recycling, re-use and recovery targets for certain categories of products, listed in Annex I, including medical devices (with the exception of implanted and infected products) and Annex III. The categories of products covered in Annex III are: 1. Temperature exchange equipment 2. Screens, monitors and equipment containing screens having a surface greater than 100 cm^2. 3. Lamps 4. Large equipment (any external dimension more than 50 cm) including medical devices. 5. Small equipment (no external dimension more than 50 cm) including medical devices. 6. Small IT and telecommunication equipment (no external dimension more than 50 cm). Since 15 August 2018, medical devices have been subject to a recovery target of 85% and a re-use and recycling target of 80% for 'large' equipment. 'Small' equipment must reach 75% for recovery and 55% for re-use and recycling. There is particular focus on the 're-use' of products, as well as on recycling and recovery, although this presents difficulties for life sciences products which are typically single-use devices in order to protect the safety of the patient. The new Medical Device Regulations and In Vitro Device Regulations require manufacturers to facilitate the safe disposal of related waste substances by the user, patient or other persons, and to identify and test procedures and measures as a result of which such devices can be safely disposed of after use. In this respect, the WEEE Directive also creates some tension in relation to the shipment of non-working medical devices across borders, as there has been a long-standing problem with electrical and electronic equipment being shipped to developing countries with the supposed intention for 're-use' when it was, in fact, going to be recycled, giving rise to risks to human health and environmental pollution.

Whilst there are guidance documents produced by regulators to assist companies with practically navigating their requirements, it remains to be seen how the ambiguities in the various legal and regulatory requirements, as set out above, are resolved in Europe. It is possible that product-specific legislation, foreshadowed in some of the above regulatory regimes, is drafted in respect of life sciences products to clarify what are otherwise significant grey areas in terms of the applicability of requirements in practice.

As ESG obligations are the subject of increasing policy focus across Europe, life science industry stakeholders must be vigilant in understanding the risks associated with non-compliance with those ESG obligations.