PRODUCT SAFETY, LIABILITY AND RECALL PREDICTIONS 2025

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1. Product liability reform will become necessary in the UK

The need for product liability reform in the UK is becoming critical. As EU reforms deal with product safety and liability, it highlights the risk of UK legislation becoming inadequate to deal with technological developments. The UK Product Regulation and Metrology Bill, if passed, will represent a significant update to the product safety framework in the UK. However, the draft Bill does not address amending the current product liability regime under the Consumer Protection Act. The 2023 consultation preceding the draft Bill paid lip service to the question of updating the UK's product liability framework when compared to the updated EU Product Liability Directive, which widens liability to include software and digital processes. The need to update UK legislation to reflect technological advances such as products with non-physical elements is a pressing issue. The current absence of specific regulation in the UK for AI generally also creates a legislative gap within product liability, to be addressed sooner rather than later. Again, the lack of clarity invites unfavourable comparison with the European Union where the renewed Product Liability Directive will amend the definition of 'product' to include software, which includes AI systems. We expect steps will be taken this year, which could take a number of forms, such as a consultation with draft legislation further down the line.

2. Representative actions will find fertile ground in products claims

Both domestic and cross-border class or collective actions across Europe will grow in number in the coming year, with product liability likely to be at the forefront of growth. The gradual and varying transposition of the provisions of the Representative Actions Directive across member states will mean that certain jurisdictions will be identified as more favourable locations for litigation. Those locations with a pre-existing and mature collective redress system may be the initial jurisdiction of choice. For example, the Netherlands has a history of collective redress actions and in 2024, permission was granted for 60,000 women to pursue an action against a breast implant manufacturer. Further significant impact on the risk of national and cross-border representative actions will be felt in 2026 as the updated Product Liability Directive also takes effect in member states. By widening liability to include software and digital processes and reducing the burden of proof on consumers seeking compensation, the prospect of collective redress measures involving product liability will only grow in the coming years.

3. Online marketplaces will face increased scrutiny under proposed legislation

Online marketplaces will face increased scrutiny over the coming year as authorities look to prevent the sale of defective, harmful and possibly illegal goods. Despite the obvious attraction of inexpensive products, there are significant concerns over the safety of many items sold. A current lack of clarity over the responsibilities resting with online marketplaces has prompted calls for regulation. In the UK, the Product Regulation and Safety Bill will seek to address this issue, identifying 'online marketplaces' as services on websites, mobile apps or other platforms used to market products, highlighting the varied nature of eCommerce. The draft Bill provides that regulations may impose product safety requirements on persons who control access to or the contents of online marketplaces, or those who act as intermediaries for those persons. The successful passing of this legislation should result in greater equity between physical and online retailers, as well as the expectation of greater enforcement and corrective measures to prevent the sale of unsafe products.

4. The MHRA will pave the way with AI Airlock

Artificial intelligence will continue to make a significant contribution to the way healthcare is delivered in the UK in the coming year. The transformative potential of AI is discussed daily but is usually accompanied by the caveat that it must be designed, developed and deployed safely. To deal with these issues, the Medicines and Healthcare products Regulatory Agency launched its AI Airlock project to address the challenges involved in regulating AI as a medical device (AIaMD). The regulatory sandbox model is a recognised mechanism to help address novel regulatory challenges and the AI Airlock applies this to healthcare. The objective is to identify the issues posed by AIaMD and to work collaboratively to understand and mitigate any risks that are uncovered while ensuring the viability of the devices in the pilot. The findings from this partnership between government, regulators and industry will then inform future projects and feed into future UK and international AIaMD guidance. Other sectors will watch with interest.

5. Advanced Therapies will break new ground

The number of Advanced Therapy Medicinal Products (ATMPs) approved by the Medicines and Healthcare products Regulatory Agency (MHRA) is expected to rise significantly in the coming years. The MHRA has only approved an average of two ATMPs annually but the UK is leading the way with clinical trials in this area despite uncertainty remaining about how long the benefits of ATMPs might persist. The potential benefits are such that the investment is vital. AMTPs including cell and gene therapies offer hope for diseases previously considered untreatable. ATMPs are already being used to treat some rare conditions, including haemophilia and spinal muscular atrophy. In some cases, these therapies can transform people's lives with just a single treatment. Therapies now in development are aiming to address conditions that affect larger patient populations, including certain types of dementia and Parkinson's disease.

6. Cost benefit assessments of new drug treatments on the NHS will continue

The National Institute for Health and Care Excellence (NICE) will continue to be faced with more cost-benefit assessments regarding innovative drugs, following the recent rejection of Lecanemab for use on the NHS. In August 2024, the Medicines and Healthcare products Regulatory Agency approved a product licence for Lecanemab for use in slowing disease progression in the early stages of Alzheimer's disease, after a thorough review of the benefits and risks. Subsequently, NICE ruled out offering the drug on the NHS, finding that the benefits were not of sufficient value to the taxpayer to justify the significant cost of making such drugs readily available on the NHS. In this instance, NICE estimated about 70,000 adults in England would have been eligible for treatment with Lecanemab were it approved. The rejection of its use on the NHS means only a small number of patients will likely access the drug in the UK, and will need to do so privately.

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