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ONE-ON-ONE INTERVIEW

PHARMACEUTICAL ADVERTISING AND REAL-WORLD EVIDENCE

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Alison Newstead advises on a broad range of product liability and regulatory issues involving electrical equipment, industrial and consumer goods, and healthcare and medical device products. She advises companies throughout the product lifecycle, from pre-market risk analysis, placing products on the market, discovery of potential safety issues, and risk management and recall action. She also has longstanding experience in coordinating pan-European litigation defence strategies in respect of claims arising out of alleged defective products.

CD: Could you provide an overview of real-world evidence (RWE) and its application in the pharmaceutical industry?

Newstead: In the context of the pharmaceutical industry, real-world data (RWD) is observational or non-interventionist research, commonly collected via electronic heath records, disease and patient registries and other healthcare technologies. Data collected in this way is often very broad and is considerably different in nature to that which is collected in a formal, and more regulated, clinical trial setting. Information produced as a result of the analysis of RWD is defined as real-world evidence (RWE). The pharmaceutical industry has long recognised that RWE can be usefully applied across the entire product lifecycle, and it is increasingly used by the industry and regulators to inform their decision making. Potential applications in this field are extensive. For example, prior to the marketing of a product, RWE can be useful in assessing the progression of a particular disease and treatment patterns. Post launch, RWE can provide valuable information to regulatory authorities in order to evaluate safety, efficacy and cost-effectiveness and assist pharmaceutical companies with issues such as pharmacovigilance and proposed label extensions.

CD: What factors have increased RWE's profile in recent years?

Newstead: The growing acceptance of the validity and value of RWE has supported a significant increase in its profile and use, particularly with a recognition that RWE can validly sit alongside randomised control trials (RCTs) and provide a much broader scope of evidence that cannot be obtained from RCTs. The increased use of technology in the healthcare sector has also influenced the growth and the demand for RWE. The development of new technologies such as wearable devices, together with increasing use of data-collecting medical devices within the home, all provide fruitful sources of information. Further advancements in technologies that gather patient data will only seek to increase the depth and scope of RWE available and augment the benefits that can be derived from it. Coupled with this continually growing source of data are advancements in RWE analytics, which are progressively allowing for deeper insights into the data collected and more prolific and accepted usage by the pharmaceutical industry and regulators.

CD: Is there growing consensus within the industry and among regulators that RWE is fundamental to understanding the safety and effectiveness of some medicines? In what ways is RWE more useful to healthcare practitioners in

facilitating better patient experience than randomised controlled trials (RCT)?

Newstead: The broader nature of RWE allows regulators, healthcare practitioners and the pharmaceutical industry to consider safety and efficacy in a real-life setting, outside the often-narrow parameters of an RCT. RCTs are commonly under representative of particular patient groups such as children, the elderly and ethnic minorities, and RWE assists in addressing these limitations. RWE allows the safety and effectiveness of medicines to be assessed within these groups and other treatment subgroups. RWE can also assist in identifying the need for patient education and how to tailor such education to particular patient requirements, thus improving the quality of care available and leading to a better patient experience. Information regarding issues such as dosing, adherence, compliance and off-label use can also be evaluated through RWE – specific patient characteristics and behaviours can also be considered. Analysis of such RWE provides pharmaceutical companies with invaluable insights into how their products are used in a real-world setting and can inform future product development and guidance.

CD: To what extent has the emergence of the coronavirus (COVID-19) pandemic highlighted the benefits of RWE collection and use?

Newstead: The coronavirus (COVID-19) pandemic had a significant global impact on the ability to conduct clinical trials. Many trials were halted due to lockdowns. Even after lockdowns eased, there remained difficulties in continuing with some trials due to the inability to conduct them in safe and effective ways or due to a refocus on COVID-19-related issues. The unprecedented circumstances presented by COVID-19 therefore necessitated an increased use of RWE within the pharmaceutical industry and highlighted the benefits of its use. The speed at which RWE could be obtained and the

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costs of doing so compared to RCTs was significant in addressing challenges presented by the pandemic. For example, RWE was used to evaluate whether existing drugs could be used to treat COVID-19, albeit with differing levels of success. RWD was also analysed to determine whether clinical trials could be carried out effectively virtually. For some trial participants, taking part in a clinical trial was the only treatment option left to them. To these individuals, the benefit of drawing on RWE in order to continue with trials was significant.

CD: How is RWE data typically used in the advertising and promotion of medical products and treatments? What criteria must be met for such advertising to be permissible under English law?

Newstead: RWE is typically used by pharmaceutical companies in advertising to support the claims that are made about their products. Such claims may appear, inter alia, on the company website, on social media, and in newspapers and magazines. Neither European Union nor UK law prevents RWE being employed in such a way. Nevertheless, the use of RWE in support of claims must still be in accordance with the applicable rules relating to the advertising of pharmaceuticals within the relevant jurisdiction. In the UK, over the counter, general sales list and pharmacy medicines can be advertised to the general public. Prescription only medicines (POMs) cannot be advertised to the general public but can be promoted to healthcare professionals. All advertising to the public must be in accordance with a number of criteria. In particular, any advertisement for a product must include its name, the name of the active ingredient – if it only contains one – information as to what the medicine can be used for and an instruction to 'always read the label' or accompanying leaflet. It is not permitted to promote a medicine use that is not covered by the "summary of product characteristics" (SPC), to make misleading claims or use pictures that may lead to a wrong self-diagnosis, to suggest that a medicine has no side effects or that the effects are guaranteed, to imply that seeing a doctor or pharmacist is not necessary, to quote recommendations by scientists, healthcare professionals or celebrities, to suggest that a medicine is different from, the same as or better than any other named product, to claim a medicine's safety or effectiveness is due to the fact it is natural, to state that normal health can be improved by taking the medicine or be affected by not taking the medicine, to direct advertising to children under the age of 16, or to provide free samples of a medicine as part of a promotion of a product. Rules for advertising medicines, including POMs, to healthcare professionals and others that can prescribe or supply products require that specific information is provided, including the name of the product, the active ingredient, and a summary of the information in the SPC regarding adverse

reactions, dosage, method of use, precautions and contraindications. Information as to the conditions that the product can be used for, the legal classification of the product and licence number and supplier must also be provided.

CD: How would you describe the risks to pharmaceutical companies of facing legal action in connection with any advertising that relies on RWE data? What essential advice would you offer to pharmaceutical companies on avoiding potential legal action by ensuring RWE data used in advertising falls within legal and regulatory parameters?

Newstead: The primary issue that pharmaceutical companies face in using RWE to support advertising claims is ensuring the reliability of the underlying data, particularly in terms of its quality and the methods that have been used in its collection and analysis. With vastly differing methods of collection and analysis being employed, companies will need to ensure that evidence is robust enough to stand up to regulatory scrutiny. There is currently limited guidance on how RWE should be used in decisions that are made in a clinical or regulatory setting. However, the need for guidance and legal frameworks has been recognised and is being acted upon across many jurisdictions, partly due to limitations identified in the use of RWE during the COVID-19 pandemic. In reality, although we are seeing an increase in the use – and robustness – of RWE, it is likely that RWE will be employed to complement the evidence obtained from RCTs. Companies can therefore ameliorate their risk by basing their advertising claims on a number of sources, not just RWE. RWE evidence will, however, remain important in respect of the groups underrepresented in RCTs, and it is such evidence that will need careful evaluation. CD